estimates that the cost for submitting a significant new use notice would be approximately $4,500 to $11,000, including a $2,500 user fee payable to EPA to offset EPA costs in processing the notice.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), EPA has determined that this rule would not have a significant impact on a substantial number of small businesses. EPA has not determined whether parties affected by this rule would likely be small businesses. However, EPA believes that the number of small businesses affected by this rule would not be substantial, even if all of the SNUR notice submitters were small firms.

C. Paperwork Reduction Act

The information collection requirements in this rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3502 et seq., and have been assigned OMB control number 2070–0012.

Public reporting burden for this collection of information is estimated to vary from 30 to 170 hours per response, with an average of 100 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM–223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

List of Subjects in 40 CFR Part 721

Chemicals, Environmental protection, Hazardous materials, Recordkeeping and reporting requirements, Significant new uses.

Dated: January 19, 1993.

William K. Reilly,
Administrator

Therefore, 40 CFR Chapter I, part 721 is proposed to be amended as follows:

PART 721 — [AMENDED]

1. The authority citation for part 721 would continue to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

2. By revising § 721.170(c)(1) to read as follows:

§ 721.170 Notification requirements for selected new chemical subetances that have completed premanufacture review.

* * * * *

(c) * * * (1) When EPA decides to establish significant new use reporting requirements under this section, EPA may designate as a significant new use any one or more of the activities set forth in subpart B of this part, as well as activities not listed in subpart B of this part. In addition, EPA may designate specific recordkeeping requirements described under subpart C of this part that are applicable to the substance.

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[FR Doc. 93–2775 Filed 2–5–93; 8:45 am]
BILLING CODE 6560–50–F

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40 CFR Part 723

[OPPTS–50594 ;FRL–3890–1]

RIN 2070–AC14

Premanufacture Notification Exemptions; Revisions of Exemptions for Polymers; Proposed Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires that persons notify EPA at least 90 days before they manufacture or import a new chemical substance for commercial purposes. Section 5(h)(4) of TSCA authorizes EPA, upon application and by rule, to exempt the manufacturer or importer of any new chemical substance from part or all of the provisions of section 5 if the Agency determines that the manufacture, processing, distribution, use, or disposal of the new chemical substance will not present an unreasonable risk of injury to human health or the environment. This proposed rule would amend the polymer exemption rule at 40 CFR 723.250 to expand the criteria for eligible polymers, reduce the information requirements, and change the timing of reporting. These proposed amendments reflect criteria developed and used by EPA to assess the hazards associated with new polymeric substances. EPA has included procedural safeguards and other conditions in the proposed exemption to ensure that these polymers will not present an unreasonable risk.

DATES: Comments must be received by April 9, 1993. If requested, EPA will conduct public hearings on the proposed rule amendments. Requests to make an oral presentation must be received by April 9, 1993.

ADDRESSES: All comments and requests to speak at the public hearing must be sent to: TSCA Document Control Office (TS–790), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E–201, 401 M St., SW., Washington, DC 20460, (Phone: 202–260–1532).

Comments should include the docket control number. The docket control number for this amendment is OPPTS–50594. Since some comments may contain confidential business information (CBI), all comments must be sent in triplicate (with additional sanitized copies if CBI is involved). Comments on this proposed rule will be placed in the rulemaking record and will be available in the TSCA Public Docket Office, Rm. NE–G–004 at the above address between 8 a.m. and 12 noon and 1 p.m. and 4 p.m., Monday through Friday, excluding public holidays.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (TS–799), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E–543–B, 401 M St., SW., Washington, DC 20460, Telephone: (202) 554–1404, TDD: (202) 554–0551.

SUPPLEMENTARY INFORMATION:

Electronic Availability: This document, along with three other related documents, OPPTS–50593, 50595, and 50596 is available as an electronic file on *The Federal Bulletin Board* at 9:00 a.m. on the date of publication in the **Federal Register**. By modem dial (202) 512–1387 or call (202) 512–1530 for disks or paper copies. This document and the three related documents are available in Postscript, Wordperfect, and ASCII.

The polymer exemption rule was originally promulgated on November 21, 1984. The supporting rationale and background for that exemption was published at 49 FR 46066 on November 21, 1984 and 46 FR 54688 on November 3, 1981. Consult those documents for further information on the objectives, rationale, and procedures for the rule and the basis for the finding that polymers eligible for exemption will not present an unreasonable risk.

I. Background

A. Statutory Authority

Section 5(a)(1) of TSCA requires that persons notify EPA at least 90 days before they manufacture or import a new chemical substance for commercial purposes. A new chemical substance is any substance that is not on the inventory of existing substances compiled by EPA under section 8(b) of TSCA. Section 5(h)(4) of TSCA authorizes EPA, upon application and by rule, to exempt the manufacturer or importer of any new chemical substance from part or all of the provisions of section 5 if the Agency determines that the manufacture, processing, distribution, use, or disposal of the new chemical substance will not present an unreasonable risk of injury to human health or the environment.

B. History

In 1984, the Agency published a TSCA section 5(h)(4) rule granting an exemption for persons who manufacture or import certain polymers, set out at 40 CFR 723.250. This rule was developed in response to petitions by chemical industry groups. Notice of receipt of the petitions from industry groups was published at 46 FR 54688 on November 3, 1981. The proposed exemption rule was published at 47 FR 33924 on August 4, 1982 and the final exemption rule was published at 49 FR 46066 on November 21, 1984.

Since promulgation of the 1984 polymer exemption rule (the "1984 exemption"), the Agency has reviewed over 9,000 polymers in the 90–day premanufacture notification (PMN) review process and over 1,500 polymers submitted as polymer exemption notices. In the course of performing hazard and risk assessments for these polymers, the Agency has established informal guidelines for identifying polymeric substances that do not present an unreasonable risk to human health or the environment. These guidelines are based on (1) an ongoing review of the available literature on the toxicity of polymers, (2) analyses of various samples of the PMN polymer data base, (3) information provided by outside groups during and subsequent to development of the 1984 exemption, and (4) the professional judgment of EPA staff scientists.

The Agency would like to bring the 1984 polymer exemption criteria into closer alignment with the internal criteria currently being used to assess hazards of polymers. The Agency believes that expansion of the 1984 exemption criteria would increase the number of polymeric substances eligible for exemption and would result in resource savings to industry and the EPA without decreasing or compromising the level of risk reduction/management afforded by a 90–day review of these same substances. The Agency is also proposing to reduce the information requirements, limit the Agency review, and change the timing of notice of manufacture for these "low risk" polymers. Overall, these amendments constitute a substantial revision of the existing rule.

II. Proposed Amendments

A. Summary of Proposed Amendments

1. *Definition of exemption category.* To be considered for exemption, substances must meet the definition of polymer in the rule. EPA is proposing to amend the definition of "polymer" to adopt the exact wording of the international definition of polymer which was agreed upon at the Organization of Economic Cooperation and Development (OECD) Expert Group Meetings on Polymers held in Toronto, Canada in January, 1990 and in Paris, France, in October, 1991. The definition is based on the 1984 polymer exemption definition with minor modifications. As with the current definition, the amended definition ensures that exempt substances have the structural characteristics common to the category of substances on which EPA has based its no unreasonable risk finding.

2. *Classes of polymers ineligible for exemption.* Section 723.250(d) of the 1984 exemption established certain classes of polymers that are ineligible for exemption. As with the 1984 exemption, polymers that degrade, decompose, or depolymerize would remain ineligible for exemption under this proposal. In addition, polymers that are prepared from monomers or other reactants that are not on the TSCA Inventory, and water-absorbing polymers with molecular weights (MW) equal to or greater than 10,000 daltons would be added to the list of ineligible polymers. This proposal would amend certain restrictions contained in the 1984 exemption for cationic polymers and polymers that contain certain particular elements. Under the proposal, the restriction on polymers that contain certain reactive functional groups that are intended or reasonably anticipated to undergo further reaction would be moved from paragraph (d) and included as part of the eligibility criteria for polymers with MW equal to or greater than 1,000 and less than 10,000 at § 723.250(e)(1). Finally, the following classes of polymers would no longer be ineligible for exemption: (a) polymers that contain less than 32 percent carbon; (b) biopolymers, their synthetic equivalents, and modifications and derivatives of biopolymers; and (c) polymers made from reactants that contain halogen atoms or cyano groups.

3. *Polymers eligible for the exemption.* Polymers with number-average MW greater than 1,000 and polyesters that are made from a specified list of reactants would remain eligible for exemption. However, under this proposal, the Agency would set limits on oligomer content and reactive functional groups for polymers with number-average MW equal to or greater than 1,000 and less than 10,000. In addition, polymers with number-average MW equal to or greater than 10,000 and restricted oligomer content would also be eligible for exemption, with certain restrictions relating to potential inhalation exposure of respirable water-insoluble polymer particles. Polyesters would remain eligible.

4. *General provisions.* To qualify for this exemption, manufacturers and importers would be required to submit an abbreviated notice within 30–calendar days after first manufacture or import of an eligible polymer instead of 21 days prior to manufacture (import) as required in the 1984 exemption. In this preamble and under the rule, references to "manufacture" and "manufacturer" include "import" and "importer", respectively, as defined in the PMN rule and as referenced in this rule.

Submission of specific information on the polymer would still be required, although the Agency proposes to eliminate certain data requirements, including information on production volume, use, residual reactant content, impurities, and byproducts.

With the elimination of the obligation to report many data elements, the use of EPA Form 7710–25 would not be required. In its place, the Agency would require submission of an abbreviated form which would limit the information requirements to the following elements: (a) submitter identification (company name, name of authorized official technical contact, telephone number of technical contact, site of manufacture or import), (b) date of commencement of manufacture or import, (c) type of polymer exemption, (d) chemical identity, and (e) certification that the polymer meets the conditions of the exemption and that submitters will provide worker protection or appropriate engineering controls to mitigate worker exposure where exposure to high MW water-insoluble polymers in respirable particle size is possible.

Under the proposal, polymer identity would be described by a Chemical Abstracts (CA) Index Name or CA Preferred Name in conformance with chemical identity requirements for all section 5 notices being proposed today in the **Federal Register** in a separate action under 40 CFR part 720. As required with the submission of all section 5 notices, submitters must provide all health and safety data in their possession or control with their notice.

Under the proposal, the Agency would maintain a separate list of exempted polymers for information retrieval purposes, but would no longer add these substances to the Inventory. Under the 1984 exemption, substances are added to the Inventory after receipt of a Notice of Commencement of Manufacture or Import. Such substances are listed with restrictions on residual monomers, reactants, and low MW species, as reported in the notice, and can only be manufactured within those prescribed limits.

As with the 1984 exemption, submitters would be required to maintain certain records. Under the proposal, submitters would be required to maintain a copy of the exemption notice at the reported site of manufacture or import, along with information that demonstrates compliance with the exemption, including analytical data that substantiates the submitter's claim of eligibility under criteria established for minimum number average MW and restricted oligomer content.

B. Discussion of the Proposal

The proposed rule adopts many of the provisions of the 1984 polymer exemption. However, as discussed above, some of the provisions of the 1984 exemption have been amended in light of the Agency's experience gained by its review of over 10,000 new polymeric substances. A discussion of these changes follows:

1. *Definition of polymer.* Under the proposal, the definition of polymer in the 1984 exemption would be revised to conform with the international definition of polymer recently adopted by OECD Member Countries, including the United States, Canada, Japan, and the Commission of European Communities. The revised definition retains the meaning and purpose of the 1984 exemption definition of polymer. The term "monomer unit", which would replace the non-standard term "internal subunit", would continue to define a grouping that is linked to two or more other molecules. Consequently, polymer molecules, defined as containing "at least three monomer units which are covalently bound to at least one other monomer unit or other reactant", would continue to require at least four precursor units, as in the current definition. The difference is that, under the proposal, at least three of the units must be internal, as opposed to only two in the current version; further, one of the non-internal groupings could come from an "other reactant" as well as from a monomer. The first change is slightly more restrictive and the second slightly less restrictive than the present definition. The net effect of the change, made to simplify agreement with protocols of the OECD, is expected to be minimal. "Monomer" and "reactant" would remain as defined in the 1984 exemption, and are consistent with the terms used for purposes of Inventory reporting and premanufacture notification, wherein "reactants" includes monomers, chain transfer and cross-linking agents, monofunctional groups that act as modifiers, and other end groups if they are incorporated into the polymer molecule.

2. *Polymers ineligible for exemption.* (a) *Exclusion of certain polymers that are cationic or anticipated to become cationic in aquatic environments.* The Agency continues to have ecotoxicity concerns for cationic polymers with specific characteristics. However, under the proposal the Agency would modify the current restriction on cationic polymers at § 723.250(d)(1) to provide that certain cationic polymers will be eligible for exemption if (i) the polymer is a solid material that is not soluble or dispersible in water and will be used only in the solid phase (for example, polymers that will be used as ion exchange beads), or (ii) the equivalent weight of cationic groups (e.g., amine, phosphonium, sulfonium) in the polymer is equal to or greater than 5,000. Equivalent weight means the ratio of the MW to the number of cationic functional groups.

The proposed modifications are based on the following considerations: (1) The Agency has concluded that if a cationic polymer is not soluble or dispersible in water, it will not be available in the aquatic environment to cause toxicity to aquatic organisms and (2) the Agency has found that polymers with a cationic functional group equivalent weight of 5,000 or greater do not have sufficient cationic characteristics to cause the environmental effects seen in materials that have higher cationic charge densities. There are many cationic polymers that are submitted as PMNs and receive low hazard ratings for health or environmental effects, but are not eligible for the polymer exemption as it is currently written. The above modifications would increase the number of polymers eligible for this exemption, without compromising the level of risk assessment/management these polymers would otherwise receive in a full 90–day PMN review.

The Agency is taking this opportunity to clarify an issue that has caused confusion to companies submitting polymer exemption notices in the past: For purposes of the 1984 polymer exemption, the Agency considers all amines (primary, secondary, tertiary amine, and quaternary ammonium) as groups that are cationic or anticipated to become cationic in aquatic environments. Based on the definition of "cationic polymer" in the 1984 exemption, any polymer that contains even one amine group is excluded from exemption. As a result, many polymers with very high amine equivalent weights (that is, very low amine content), such as polyamides, are excluded from the 1984 exemption. Under this proposal, polymers containing cationic functional groups may be eligible for exemption if the total equivalent weight of cationic groups is 5,000 or greater. All amine containing polymers with amine equivalent weights of less than 5,000 would be excluded from eligibility under this category.

(b) *Exclusion of polymers with certain weight content of certain elements.* The rule would continue to exclude from eligibility for exemption polymers containing certain levels of particular elements if they are present as an integral part of the polymer structure, or present as counterions in the polymer.

Elemental limitations were defined in the 1984 exemption and the Agency believes that the discussion and rationale for many of the elemental limitations in the 1984 exemption rule preamble and 1982 proposed rule are, in general, appropriate for this proposed rule. However, the Agency is proposing to expand the list of allowable elements set out at § 723.250(d)(2)(ii)(B) and (C) to include chlorine, bromine, and iodine as the monatomic counterions; and fluorine, chlorine, bromine, and iodine as covalently bound to carbon. Currently, the Agency's internal review criteria do not identify concerns for polymers based solely on the fact that the above mentioned halogens are present in a polymeric substance as a covalently bound substituent or as a counterion. Therefore, the EPA believes it appropriate to allow for these elements to be present in exemptible polymers. The provisions at proposed § 723.250(e)(1) would exclude reactive

functional groups, including reactive halogen containing groups, and would continue to limit the exemptible substances to those determined to be of lowest concern. The Agency solicits comment on and suggestions (with rationale) for these and any other elements to be added to these categories.

(c) *Exclusion of polymers that degrade, decompose, or depolymerize.* The rule would continue the exclusion at § 723.250(d)(3) for polymers that are designed or reasonably anticipated to substantially degrade, decompose, or depolymerize, including those polymers that could substantially decompose after manufacture and use, even though they are not actually intended to do so. The Agency believes that such polymers are likely to degrade to low MW species and/or residual reactants which present some of the major risks associated with such polymers. The 1984 exemption contains this same provision, and discussions on the topic can be found in the 1984 exemption rule and the 1982 proposed rule. The Agency believes the discussion and rationale for excluding polymers that may degrade, decompose, or depolymerize is appropriate for this proposed rule as well.

(d) *Exclusion of polymers that are prepared from monomers or other reactants that are not already on the TSCA inventory.* Under the proposal, polymers that are prepared from monomers or other reactants that are not on the TSCA Inventory would be ineligible for exemption at § 723.250(d)(4). Hazard concerns for polymers are often based on a concern for residual monomers or other reactants in the polymer. Under the proposal, information on levels of residual monomers or other reactants would no longer be required on the notice form. Instead, the evaluation and regulation of any potential risks posed by existing chemicals that may be present as residuals in the polymer would be addressed by a separate EPA program under other TSCA authorities such as section 4 and section 6. Accordingly, the Agency proposes to restrict this exemption to those polymers manufactured using only Inventory-listed constituent monomers, chain transfer agents, initiators, or other substances that are present as an integral part of the polymer structure or are present as counterions in the polymer. Consequently, the Agency will still have the option of reviewing polymers that contain new chemical monomers or other reactants through the full PMN process and regulating any new substances of concern that may be present as residual monomers or reactants.

(e) *Exclusion of water-absorbing polymers with number-average MW equal to or greater than 10,000 daltons.* Under the proposal, water-absorbing polymers having MW of 10,000 daltons or greater would be ineligible for the exemption at § 723.250(d)(5). A water-absorbing polymer is defined as a polymeric substance that, either in whole or in part, increases its volume when in contact with water. EPA believes that this category of polymers should not be eligible for the polymer exemption based on TSCA section 8(e) data recently received by the Agency on a water-absorbing polyacrylate polymer with a MW in excess of 1 million daltons. Preliminary data report squamous cell carcinoma and bronchio-alveolar carcinomas in a 2–year inhalation study in rats. The exposure concentrations were 0.05, 0.2, and 0.8 mg/m^3. Preliminary pathology reports state that cancer was observed in the two highest concentrations. Since this polymer has a MW in excess of 1 million daltons, no remaining reactive functionalities, and no residuals with MW less than 1,000 daltons, the Agency believes that the water-absorbing properties of the polymer may have a role in the carcinogenicity findings. Based on the toxicity data that have been received by EPA to date, the Agency is unable to establish an exact MW limit for water-absorbing polymers. However, the Agency believes that it is reasonable to set the number-average MW exclusion for water-absorbing polymers at 10,000 daltons. As discussed later in this Unit, polymers with a number-average MW of less than 10,000, in general, can be expected to be absorbed by the lung and therefore have different detoxification mechanisms available to mitigate potential health hazards.

3. *Elimination of specific exclusions contained in the 1984 exemption.* In the current proposal, the Agency has removed three of the exclusion criteria present in the 1984 exemption at § 723.250(d)(2), (4), and (5) including (a) polymers containing less than 32 percent carbon, (b) biopolymers, and (c) polymers manufactured from reactants containing halogen atoms or cyano groups. A discussion on why these limitations were removed is presented below.

a. *Polymers containing less than 32 percent carbon.* The 1984 rule at § 723.250(d)(2) excludes from exemption eligible polymers with less than 32 percent carbon by weight. This exclusion was intended to limit availability of the exemption to the types of polymers that have been frequently reviewed in the New Chemicals Program. The requirement that polymers must contain greater than 32 percent carbon was an added safeguard to prevent exotic, or unfamiliar, types of polymers from being eligible for the exemption. Based on its experience reviewing over 10,000 section 5 notices for polymers since 1979, EPA has seen very few polymers with less than 32 percent carbon and those notices seen have been rated as of low concern.

The Agency now believes that the other criteria that must be met for a substance to qualify for the polymer exemptions will provide sufficient restriction to the types of polymers that would be eligible for exemption, and therefore removal of the 32 percent carbon limitation is justified.

b. *Biopolymers.* The 1984 rule excludes from exemption eligibility at § 723.250(d)(4) biopolymers, synthetic equivalents of biopolymers, and derivatives and modifications of biopolymers. The Agency now believes that this condition can be removed entirely. Biopolymers were originally excluded from the polymer exemption based on EPA's limited experience with these compounds, the variety of substances within the class, and the potential wide range of uses for such polymers. The number of biopolymers reviewed as full PMNs has been small, and therefore EPA still has only limited experience with these compounds. However, EPA has had sufficient experience with many other classes of polymers to believe that biopolymers that meet the exemption criteria will not pose an unreasonable risk of injury to human health or the environment. The Agency believes that biopolymers that may be of concern, such as proteins and antibodies, would not be eligible for the polymer exemption due to the fact that they would not fall within the polymer definition in the exemption because they have a discrete MW. In order to be a "polymer", polymer molecules must be distributed over a wide range of MW. As an example, the highly toxic protein ricin has a definite structure and a discrete MW and would therefore not be eligible for the polymer exemption.

c. *Polymers manufactured from reactants containing halogen atoms or cyano groups.* Based on an analysis of health and ecotoxicity concerns for polymers received as non-exempt PMNs subject to the 90–day review, the Agency now believes that this requirement is unnecessarily restrictive and should be eliminated altogether.

The Agency's intent in excluding polymers that contain halogen or cyano groups from exemption eligibility was, as stated in the polymer exemption rule

of 1984, to "exclude polymers that contain low MW species or residual substances composed of halogen atoms or cyano groups". Information from the PMN database shows that when the content of low MW species of cyano- or halogen-containing polymers is below the levels specified by the proposed eligibility requirements for polymers with number-average MW of 1,000 or greater and less than 10,000 (and oligomer content less than 10 percent below MW 500 and less than 25 percent below MW 1,000), the EPA, in general, has low concern for the polymer. Further, EPA also has low concern for polymers with MW of 10,000 or greater (and oligomer content less than 2 percent below MW 500 and less than 5 percent below MW 1,000). Since, in the proposed exemption, eligible polymers may be made only from Inventory-listed monomers or other reactants, any remaining concerns over residual monomers can be dealt with under other TSCA authorities such as section 6. The proposed exemption criteria address the Agency's concerns for all low MW species including those containing halogen or cyano groups. It is hoped that the benefit of allowing manufacturers to commence production of more polymers eligible for exemption will provide incentive to submitters to manufacture materials with low concentrations of oligomeric species.

Further, as a matter of policy, EPA has not taken action on a PMN polymer under section 5(e) when the only concern was for an existing chemical present as unreacted monomer, i.e., residual monomer. Under this proposal, only polymers manufactured from Inventory-listed monomers would be eligible for exemption. Since the proposed criteria would restrict low MW species and any residual monomers would be existing chemical substances that would be addressed by a separate EPA program, the Agency believes that a separate exclusion from polymer exemption eligibility for halogen- and cyano- containing polymers is no longer necessary. The Agency believes that concerns for residual monomers in general and specifically those containing halogen or cyano groups would best be handled by an existing chemicals program initiative, and not on a case-by-case basis under section 5 in the new chemicals program.

4. *Polymers eligible for the exemption (§ 723.250).* The Agency is proposing to amend the exemption criteria for polymers of 1,000 MW or greater by establishing two MW ranges with restricted oligomer content. Section 723.250(e)(1) would set out exemption criteria for polymers with number-average MW equal to or greater than 1,000 and less than 10,000, while § 723.250(e)(2) would set out criteria for polymers with number-average MW equal to or greater than 10,000. The exemption criteria for polyester polymers manufactured using certain specified precursors would be retained under this proposal and redesignated at § 723.250(e)(3). Under the proposal, polymers eligible for exemption include the following:

a. *Polymers with number-average MW equal to or greater than 1,000 and less than 10,000.* Section 723.250(e)(1) would exempt polymers with number average MW equal to or greater than 1,000 and less than 10,000 (and oligomer content less than 10 percent below MW 500 and less than 25 percent below MW 1,000) provided the polymer also meets the following criterion: the polymer may not contain reactive functional groups that are intended or reasonably anticipated to undergo further reaction as specified in § 723.250(e)(1)(ii).

i. *Restrictions on number average MW and oligomer content.* As stated in the preamble language to the 1984 exemption published in the **Federal Register** on November 21, 1984 (49 FR 46081) the selection of MW as a risk-limiting criterion rests on two principles. First, a chemical must be absorbed by an organism in order to cause an adverse health or ecological effect, other than direct contact effects. Secondly, the ability of a molecule to pass through membranes and therefore be absorbed by organisms generally decreases with increasing MW (size).

Based on these principles, the Agency believes that low MW species content provides an appropriate indication of the concerns that EPA has for polymers, namely, the content of potentially absorbable low MW compounds. The proposal would include restrictions on the percentage of low MW components directly derived from the monomers or other reactants for § 723.250(e)(1) polymers. The proposed criteria would require that oligomer content be less than 10 percent below MW 500 and less than 25 percent below MW 1,000. These values are based on a retrospective study conducted on over 100 polymers rated as having low concern, including their accompanying test data, an assessment of their potential to cause human health effects and environmental toxicity, and a rating of the expected amount of toxicity. This study, entitled "Evaluation of Tentative Terminations in New Chemical Review," is available in the public docket for this rulemaking (OPPTS–50594).

The 1984 polymer exemption requires companies to supply information on low MW species content, but these data are not part of the criteria for eligibility. Based on the 1984 polymer exemption, companies are legally bound to manufacture polymers with equal to or less than the percent of low MW species and residual monomer concentrations reported in the polymer exemption notice for a new substance. If a company desires to manufacture a polymer with higher amounts of low MW species or residual reactants than were reported in the polymer exemption notice, then a second polymer exemption application or a PMN must be filed. In the proposed approach, companies would be free to manufacture a polymer for which they had filed a polymer exemption notice with any MW characteristics or residual reactant content desired, as long as the percentages of low MW species did not exceed the levels specified in the exemption criteria.

ii. *Restriction on reactive functional groups.* The rule would exclude from eligibility under the § 723.250(e)(1) criterion certain polymers that contain reactive functional groups that are intended or can reasonably be anticipated to undergo further reaction. The rule also would amend certain restrictions in the 1984 exemption.

As discussed in the 1984 exemption and the 1982 proposed rule, polymers that contain reactive functional groups may be capable of reacting with tissues or other chemical constituents of living organisms. Absorption of polymers containing reactive functional groups is also plausible since reactive groups often cause sufficient irritation to disrupt normal cell membrane barriers and facilitate penetration.

Consistent with § 723.250(d)(6)(ii) of the 1984 exemption, polymers that contain certain reactive functional groups that generally lack reactivity in biological settings would still be eligible for the exemption under this proposal. Therefore, under § 723.250(e)(1)(ii)(A) of the proposal, polymers containing only the following reactive and/or other functional groups would remain eligible for the exemption: carboxylic acid groups, aliphatic hydroxyl groups, unconjugated olefinic groups that are considered "ordinary", butenedioic acid groups, and those containing conjugated olefinic groups contained in naturally-occurring fats, oils, and carboxylic acids. Further, based on the Agency's experience in reviewing polymers since the 1984 exemption was promulgated, EPA now believes that the following groups generally lack or have low adverse reactivity in biological settings, and is therefore proposing to add them

to the above list: blocked isocyanates (including ketoxime-blocked isocyanates) thiols, unconjugated nitrile groups, and halogens (except reactive halogen-containing groups such as benzylic or allylic halides).

iii. *Approach to establishing other reactive functional group equivalent weights.* In the 1984 exemption, the Agency established equivalent weight criteria which allowed low concentrations of reactive functional groups to be present in the polymer molecules. At that time it was believed that a level of less than 1 gram-formula weight of reactive functional groups in 10,000 grams of polymer was sufficient to ensure that the reactive functional group was substantially diluted by polymeric material. Based on the Agency's experience in reviewing polymers since the 1984 exemption was promulgated, EPA now believes that the reactive functional group equivalent weight of 10,000 can be lowered to 5,000. In addition, the Agency is also proposing to establish allowable equivalent weights at 1,000 for the combined weight of certain polymer reactive functional groups other than those in § 723.250(e)(1)(ii)(A), which would not have an equivalent weight limit, based on the Agency's lower level of concern for these reactive groups. These groups would include the following: acid halides; acid anhydrides; aldehydes; hemiacetals; methylolamides, -amines or -ureas; greater than C2 alkoxysilanes; allyl ethers, conjugated olefins; cyanates; epoxides; imines; and unsubstituted positions *ortho* or *para* to phenolichydroxyl.

All other reactive functional groups would be required to have a combined equivalent weight of 5,000 or greater, including pendant acrylates and methacrylates, aziridines, carbodiimides, halosilanes, hydrosilanes, hydrazines, isocyanates, isothiocyanates, *alpha* or *beta* lactones, methoxy or ethoxy silanes, vinyl sulfones or analogous compounds and any reactive functional group not listed at § 723.250(e)(1)(ii)(A) or (B).

This proposal would increase the number of polymers eligible for exemption under this category; however, the added complexity of this approach may not be justified relative to the number of additional polymers that might be made eligible. Specifically, the Agency is concerned that smaller businesses or those with limited technical resources would have trouble interpreting the exemption criteria for reactive functional groups, if the groups are complicated, and may choose not to use the exemption for eligible polymers. Such persons would, of course, have the option of using 5,000 as the equivalent weight if they are uncertain whether a particular reactive functional group is listed under § 723.250(e)(1)(ii)(A) and (B). Therefore, the Agency is seeking comment on this approach and the alternative one discussed later in this document.

EPA believes that restrictions on reactive functional groups are not necessary for polymers with a number-average MW equal to or greater than 10,000 because polymers of this size would not be expected to be absorbed by biological systems.

b. *Polymers with number-average MW equal to 10,000 or greater.* Section 723.250(e)(2) would exempt polymers with number average MW equal to 10,000 or greater (and oligomer content less than 2 percent below MW 500 and less than 5 percent below MW 1,000), provided the submitter evaluates the potential for inhalation exposure to respirable particles of water-insoluble polymers and provides adequate notification and appropriate protective measures, if warranted, as specified at § 723.250(e)(2)(i) through (e)(2)(v) of the proposed rule. The Agency is proposing to establish a separate category for polymers with number-average MW equal to or greater than 10,000 because this category of polymers is not readily absorbable by any route of exposure; further, low MW species below 500 and 1,000 will be restricted under this proposal. EPA does, however, have a concern for potential effects that may be caused by inhalation of respirable particles of water-insoluble high MW polymers. In the 1984 exemption, the Agency discussed its concern for potential health risks such as the development of fibrosis of the lung or other pulmonary effects that may result upon inhalation of polymers in particulate form. At that time the Agency believed that such exposure to polymer particulates was generally limited and expected to be of low concern. The Agency now believes that it may be inappropriate to make a "no unreasonable risk" finding for high MW water-insoluble polymers without requiring evaluation of potential exposure to respirable particles of such polymers. Thus far, the Agency has no data to warrant any concern for inhalation toxicity for water soluble polymers.

The Agency has received TSCA section 8(e) data that report irreversible lung damage on experimental animals when respirable size water-insoluble polymer aerosols are inhaled. Pulmonary damage induced by inhalation exposure to the subject polymers includes chronic inflammatory response, lymphoid hyperplasia in mediastinal or bronchial lymph nodes, nodular histiocytosis in mediastinal or bronchial lymph nodes, fibrotic alveolar lesions, interstitial fibrosis and alveolar tumors. The data also demonstrate that the onset of the polymer-induced damage may be delayed for as long as 6 months after exposure. The toxicity may be a result of "overloading" the clearance mechanisms of the lung; however, at this time the Agency does not have sufficient toxicity data to either confirm or discount the "overload" theory. The Agency does not have sufficient data to determine the precise MW and/or structural considerations that may facilitate the mechanisms causing toxicity, although data received to date indicate that lung toxicity is produced by water-insoluble polymers with a MW as low as 70,000 and at respirable concentrations as low as 4 mg/m^3.

In light of these data, EPA has concerns for lung effects from water-insoluble polymers with MW of 70,000 or greater. Although to date EPA has no inhalation data on polymers eligible for the proposed exemption with MW of less than 70,000, adverse lung effects resulting from inhalation exposure to water-insoluble polymers with MW of 10,000–70,000 cannot be ruled out. Substances in the 10,000–70,000 MW range are, in general, not readily absorbed by any route of exposure. Thus if alternative lung clearance mechanisms are overloaded, lung toxicity would be expected to occur. Polymers with a MW of less than 10,000, in general, can be expected to be absorbed by the lung and therefore have different detoxification mechanisms available to mitigate potential health hazards. Further, EPA does not expect water-soluble polymers to exhibit lung toxicity because they are expected to rapidly clear the respiratory tract and therefore not cause an overloading effect. The Agency requests comment on the MW range anticipated to produce toxicity.

Currently, the New Chemicals Program, in response to the TSCA section 8(e) data referenced above, is more rigorously evaluating the inhalation exposure potential of water-insoluble polymers with MW greater than or equal to 70,000 that are submitted as PMNs or polymer exemption applications. In cases where the manufacturing, processing, or use of such polymers is expected to result in exposure to respirable particles, the Agency would use its regulatory authority under section 5(e) to limit human exposure. Under section 5(e) of

TSCA, the Agency can limit or control the activities associated with a chemical substance if such activities may present an unreasonable risk to human health or the environment.

Under today's proposal, polymers ranging from 10,000–70,000 daltons (with the exception of water-absorbing polymers ineligible at § 723.250(d)(5)) would be eligible for the exemption, provided the manufacturer evaluates potential inhalation exposure, and if such exposure exists, implements certain procedural safeguards to control inhalation exposure. This approach would allow the Agency to make a determination for purposes of section 5(h)(4) of TSCA that this category of polymers will not present an unreasonable risk to human health or the environment. Further, until more definitive data on the inhalation toxicity of high MW polymers are submitted to EPA for review, the Agency believes that the additional requirements for this MW range are a reasonable response to the TSCA section 8(e) data received.

The Agency has considered several alternatives for dealing with potential lung effects in the context of the polymer exemption which are described in Unit III of this preamble. Under the proposal, manufacturers of water-insoluble polymers with MW of 10,000 or greater would be required to certify that they are aware of the potential for harmful lung effects upon inhalation of certain high MW polymers, and would provide, at a minimum, worker protection in the form of a NIOSH-approved category 21C, 23C, or equivalent respirators if there is a potential for inhalation exposure to any respirable particulates of the exempted polymer. Alternatively, manufacturers could insure that workplace respirable dust does not exceed 0.5 mg/m^3, as an 8–hour TWA based on present data, to reduce worker exposure. Manufacturers would be required to notify processors and industrial users of potential inhalation exposures and would be required to cease distribution to customers who failed to provide the prescribed worker protection measures.

The Agency believes that a level of 0.5 mg/m^3 will provide an adequate margin of safety in light of the data and that this level is technologically feasible. The Agency requests comment on typical airborne concentrations, particle sizes and respirable content of commercial products.

The Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) for respirable particulates, not otherwise regulated is 5 mg/m^3 (29 CFR 1910.1000) as an 8–hour time-weighted average (TWA). EPA assumes that companies are in compliance with the OSHA PEL and are controlling employee exposure to 5 mg/m^3 or below by using engineering controls, respiratory protection, etc., as required by the standard. However, in light of the data noted above, EPA believes it is reasonable to require a lower limit for respirable particulates of water-insoluble polymers. To achieve compliance with the 0.5 mg/m^3 exposure limit proposed by EPA, additional engineering controls, work practices, good housekeeping practices, or different respiratory protection may be needed. EPA prefers the use of process changes, engineering controls, and work practices to reduce inhalation exposure to acceptable levels, and believes that in many cases, companies already in compliance with the OSHA PEL of 5 mg/m^3 would be able to achieve the 0.5 mg/m^3 exposure limit by modifying and improving the existing work practices, housekeeping, and maintenance practices, to reduce the amount of dust generated, or by upgrading engineering controls or respiratory protection currently used. However, EPA realizes that the OSHA PEL does not apply to all workplaces and that there are different PELs for different industry groups such as construction. EPA requests comments and information on typical airborne concentrations of respirable high MW polymers and airborne particle size distributions measured in the workplace, and on process changes, engineering controls, work practices, etc., that would be needed to meet the exposure limit of 0.5 mg/m^3 for respirable particulates of high MW polymers.

Examples of process changes to reduce inhalation exposure include manufacturing, processing, and using materials in solution, in pellet form, or as a wet cake instead of drying the material and handling it as a powder or in other particulate forms. Application methods other than spray application (e.g., roller coating, dip coating , etc.) can also reduce inhalation exposure as the potential for aerosol generation is reduced. In addition, good housekeeping practices, appropriate maintenance and good work practices, (e.g., wet mopping or vacuuming spills instead of dry sweeping, repair of leaks as soon as possible, etc.) can also reduce the amount of dust generated, and the potential for inhalation exposure.

Where engineering controls are employed as an alternative to respirators, the initial exposure assessment must be sufficient to insure that the airborne concentration of respirable high MW polymers does not exceed 0.5 mg/m^3. In such cases, EPA recommends but would not require personal monitoring and requests comments on appropriate collection devices. Respirable cyclone dust samplers which are commonly used to differentiate the respirable fraction from larger particles in the aerosol may be inappropriate for high MW polymer materials. The performance of the 10 mm plastic cyclone (which is commonly used to collect respirable dust) has been criticized because an electric charge can accumulate on the plastic and distort the collection characteristics. EPA encourages the use of an impactor or other suitable collection device for sample collection for high MW polymer materials and is interested in comments.

c. *Polyester polymers manufactured solely from reactants listed at § 723.250(e)(3).* The Agency has had sufficient experience in reviewing polymer exemption notices for polyester polymers that are prepared using reactants specified in the 1984 exemption rule that the Agency does not believe such polymers represent a risk to human health or the environment. Accordingly, the Agency believes that these polyester polymers should continue to be eligible for exemption. The only change EPA is proposing to this exemption is the deletion of a footnote that would no longer be applicable, because under the proposal all monomers and reactants used to manufacture the polymer must be on the TSCA Inventory.

There are many polyester polymer reactants that are not included in the 1984 polyester exemption list, and the Agency has had requests to expand the list. Except for the chemicals currently listed in the 1984 exemption rule, the Agency has no experience in evaluating polyester reactants in a shortened review period. Therefore, the Agency cannot make a "no unreasonable risk" finding for "new" polyester reactants without conducting a limited review of the polymers that contain the "new" reactants.

The Agency solicits comment on the relative merit of expanding the list of polyester reactants and also requests suggestions and supporting data for adding other polyester reactants to the current list. Potential health or environmental effects of these reactants will be evaluated by the Agency and any low concern reactants may be added to the list in the final rule. However, in the case of anhydrides, which were inadvertently listed in the title of di and tri basic acid reactants in the 1984 exemption, but not included as specific reactants, EPA still does not believe that a "no unreasonable risk" finding can be

made for this class of substances that are used as reactants for polyester polymers. Certain anhydrides are known to be respiratory and/or dermal sensitizers and cause such effects at concentrations as low as 50 mg/m^3. Based on these concerns, the Agency believes it cannot justify the addition of anhydrides to the list of polyester reactants.

5. *Determination of eligibility.* The Agency believes that, when a polymer is manufactured under the terms of the proposed exemption, it is reasonable for the manufacturer to take on a greater burden to demonstrate eligibility than under the 1984 exemption because EPA is proposing to eliminate its pre-manufacturing review of these notices. Under the 1984 exemption, the Agency did not require that submitters perform analytical measurements of the physical and chemical properties of polymers, but allowed manufacturers to determine compliance with the exemption conditions on whatever basis deemed appropriate by the manufacturer. These included using past experience by correlating observed or measured values of the properties of similar polymers to the polymer in question, using stoichiometric relationships based on knowledge of the starting materials and expected reactions, or using knowledge or process and purification steps.

Under this proposal, the Agency would no longer review the exemption notices, prior to manufacture of the exempted polymer. Consequently, the Agency expects the manufacturer to take the steps necessary to ensure that a chemical substance is eligible for exemption. Therefore, the Agency believes that it is necessary to require that a manufacturer maintain appropriate data to demonstrate that a substance meets the eligibility criteria for § 723.250(e)(1) and (e)(2) to ensure compliance with the exemption. This requirement would not apply to the polyester exemption at paragraph (e)(3), since this category does not impose a minimum number-average MW or restrict oligomer content as criteria for eligibility.

Under § 723.250(l)(2)(ii)(C) and (D) of the proposal, the Agency would require that manufacturers of exempt substances at (e)(1) and (e)(2) maintain appropriate analytical data to demonstrate that the polymer meets the minimum number average MW and corresponding restrictions on oligomer content. The Agency would not specify a particular analytical method to demonstrate compliance with the eligibility criteria, but would allow the manufacturer to use an appropriate method of analysis that generates the data to verify compliance with the criteria, such as gel permeation chromatography or vapor pressure osmometry. Performance of such analysis would be required prior to commencement of manufacture or import in accordance with the exemption.

EPA expects that if conditions, such as reaction temperature or sources for feedstock change, manufacturers will take steps to determine the effect of such a change so as to ensure continued compliance with the exemption. The rule would require that manufacturers maintain, at the site of manufacture, records demonstrating a substance's eligibility, along with a copy of the notice submitted to the Agency upon commencement of manufacture of the exempted substance. Manufacturers must follow the provisions of the exemption for research and development (R&D) activities during the period of evaluation of eligibility of a substance under the exemption criteria prior to actual manufacture under the exemption provisions. Such R&D activities would be subject to the R&D procedural and recordkeeping provisions in the PMN rule at § 720.36 and § 720.78, respectively.

6. *Timing of notification.* The notice procedure being proposed at § 723.250(f) would require that the notice be filed within 30 days after manufacture or importation for commercial purposes instead of 21 days prior to manufacture of an eligible polymer as under the current exemption. This would allow EPA to capture some basic information on the exempted polymers and their manufacturers/importers with minimal reporting burden on the submitter. EPA recognizes that one of the major benefits of this exemption is that it allows companies to respond more rapidly to market demand and to introduce new chemical substances more quickly into commerce.

7. *Information requirements.* The Agency is proposing to amend § 723.250(f) to eliminate certain data elements. To accommodate the abbreviated information requirements, the Agency is proposing to replace EPA Form No.7710–25 at § 723.250(f)(1) with a modified form. Some of the 1984 exemption information requirements at § 723.250(f)(2) will remain the same, including manufacturer's name, type of exemption, generic chemical identity, and test data and other data. Other provisions of the notice contents in the 1984 exemption at § 723.250(f)(2) would be revised as follows:

a. *Site of manufacture.* The Agency is proposing to amend this requirement at § 723.250(f)(2)(iii) to also include site of import for an imported exempt polymer.

b. *Chemical identity.* The proposal would amend the chemical identity information requirements at § 723.250(f)(2)(iv)(A) to require a Chemical Abstracts (CA) Index Name or CA Preferred Name, CAS Registry number (or EPA Inventory accession or PMN number) for each reactant used at greater than 2 percent (by weight) to manufacture the polymer, or alternatively, incorporated at greater than 2 percent (by weight) in the polymer. Elsewhere in today's **Federal Register**, EPA is proposing to amend the "Two Percent Rule" to allow submitters greater flexibility in determining the amount of monomer or reactant used in the manufacture of a polymer. Manufacturers who choose to use the "incorporated" method, would be required at § 723.250(f)(2)(iv)(A) to maintain appropriate analytical data to demonstrate compliance with the "Two Percent Rule". Any reactant charged to the reactor at greater than 2 percent (by weight) must be identified in the polymer name unless data are developed to ensure that the reactant is incorporated at 2 percent or less in the polymer. The proposal will eliminate the requirement for maximum percentage composition for each monomer or other reactant used to manufacture the polymer, and manufacturers would no longer be required to specify any reactants used at 2 weight percent or less in the manufacture of the polymer unless the manufacturer wishes to include such reactants as part of the polymer chemical identity. Further discussion on the "Two Percent Rule" rule appears below.

Under the proposal, the manufacturer would also be required at § 723.250(l)(2)(iv)(C) to provide the CA Index Name or CA Preferred Name for the polymer and any CAS Registry Number that exists for the polymer. This requirement would be consistent with the Agency's proposal published elsewhere in today's **Federal Register** to require that submitters use CAS nomenclature in all section 5 notices.

Under the proposal, number-average MW, maximum weight percent of each monomer or other reactant that will be present as residual in the polymer as manufactured for commercial purposes, and impurity information will no longer be required on the notice form. However, under § 723.250(l)(2)(C) and (D), the manufacturer would be required to maintain appropriate analytical data to demonstrate that an exempted polymer at § 723.250(e)(1) or (e)(2) meets the specific number-average MW

and restricted oligomer content criteria, as discussed above under Unit II.B.5 of this preamble. This proposal would allow the company to make the polymer with MW ranges, or residual reactant concentrations, etc., as the company desires, provided that these values fall within the exemption criteria.

Further, production volume and category of use would no longer be required since the exemption criteria are based primarily on a "low hazard" determination of the eligible polymer itself and do not require an exposure evaluation, except in the case of inhalation exposure to water-insoluble high MW polymers as discussed elsewhere in this document.

c. *Certification.* This requirement would be amended to require certification at § 723.250(f)(2)(vii)(E) that the manufacturer of a water-insoluble polymer with a number average MW equal to or greater than 10,000 is aware of the potential for harmful lung effects upon inhalation of respirable particles of certain high MW polymers and would comply with the evaluation and notification requirements at § 723.250(e)(2). Certification that the person submitting the notice has provided a currently correct chemical identity for the polymer using CAS nomenclature would also be required under the proposal at § 723.250(f)(2)(vii)(F).

8. *Two percent rule for polymers.* In a separate regulatory action, the Agency is proposing to amend the "Two Percent Rule" for polymers to allow submitters greater flexibility in determining the amount of monomer or reactant used in the manufacture of a polymer. EPA believes that allowing submitters to report on the basis of amount incorporated in the polymer as an alternative to the current practice of requiring reporting based on the amount "charged" to the reactor will provide a better indicator of physical, chemical, and toxicological properties of polymers. At the same time, this will allow manufacturers greater flexibility in commercial innovation, reduce the number of PMNs representing slight variations in polymer composition, and provide greater consistency with international reporting policies. Further discussion of this issue is contained in the proposed PMN rule amendments being published elsewhere in this issue of the **Federal Register**.

9. *Receipt and review of notice.* Under paragraph (g), the Agency would continue to announce receipt of exemption notices in the **Federal Register**. However, the Agency would no longer review the exemption notice since the proposal would require submission of the notice within 30 days of manufacture of an exempted substance under terms of the exemption. In order to ensure compliance with the provisions of this exemption, the Agency expects to include as part of its on-going inspection process, an examination of pertinent records documenting compliance with the exemption requirements.

10. *Recordkeeping.* EPA believes that recordkeeping requirements are an essential component of an effective exemption enforcement program and would retain and modify this provision in the proposed rule at § 723.250(l). Documentation of information in the notice would be used by enforcement personnel to determine compliance. The recordkeeping requirements would be amended at § 723.250(l)(2)(i) to require that the manufacturer maintain a copy of the completed exemption form at the reported site of manufacture or the site of import. Under the provisions of the exemption, the manufacturer would also be required at § 723.250(l)(2)(ii)(C) and (D) to maintain documentation which demonstrates that the first commercial batch of polymer manufactured for commercial purposes under the exemption meets the eligibility criteria for minimum number average MW and restricted oligomer content for (e)(1) and (e)(2) polymers. The proposed regulations at § 723.250(l)(2)(ii)(D) would also require the generation of subsequent documentation to ensure compliance with the exemption if conditions occur, such as reaction temperature or sources for feedstock change, which result in a significant change in the manufacturing process. Further, manufacturers using the method of incorporation for determining compliance with the "Two Percent Rule" would be required to maintain documentation at § 723.250(l)(2)(ii)(E).

Under the proposal, the manufacturer would further be required at § 723.250(l)(2)(iv) to maintain documentation of the nature and method of notification of risk of inhalation toxicity for water-insoluble polymers with number average MW equal to or greater than 10,000 as specified at § 723.250(e)(2)(iii) and (iv).

11. *Inspections.* Under the proposal, EPA would continue to periodically inspect all companies which have submitted TSCA section 5 notices, including exemptions. Those submitters with violations may be inspected more frequently.

To determine compliance with the exemption, the EPA inspector will focus on the information in the exemption notice and the company's records, including the analytical data documenting the substance's eligibility under the exemption.

12. *Revocation.* The proposed rule includes provisions to revoke the exemption for an exempted polymer and require a full PMN review if, subsequent to granting the exemption, EPA obtains information indicating that a particular polymer or category of polymers may present an unreasonable risk of injury to health or the environment. As new data are developed for certain polymers or category of polymers (such as the toxicity of high MW polymers), the Agency may conclude that an exempt polymer causes unacceptable risks. This is a change from the corresponding provision at § 723.250(p) The current provision contains two separate provisions for notification of ineligibility, one that is applicable during the period from notice submission until commencement of manufacture, and a second that applies after commencement of manufacture. To reflect the proposed elimination of the 21-day review period, the proposed revocation provision would provide a single procedure.

Under this proposed rule, if the polymer were eligible for exemption, the polymer would not be listed on the Inventory of existing substances. As a result, manufacture of the substance by anyone other than the company submitting the exemption application is precluded. Since the exempted polymer would still be a "new" chemical substance, revocation of exemption status under the terms of the proposed rule would be accomplished directly, without utilizing other TSCA authorities.

13. *Confidentiality.* The proposed rule at § 723.250(h) has retained essentially the same provisions for confidentiality as the 1984 exemption and the final premanufacture notice rule (§ § 720.80, 720.85, and 720.90), including a requirement that submitters provide a sanitized copy of the exemption notice in which all confidential information has been deleted. Please consult the preamble to the 1984 exemption (49 FR 46080) for a further discussion of this issue.

14. *Inventory status of exempted polymer.* The TSCA Chemical Substance Inventory (Inventory) is a list of substances that are manufactured, imported, or distributed for a commercial purpose in the United States. Unless specifically excluded from TSCA reporting requirements, a substance not already included on the Inventory must undergo PMN review at least 90 days before commercial manufacture or importation can begin.

Upon the completion of the 90–day review period, a Notice of Commencement (NOC) must be submitted within 30 days following the commencement of manufacture or importation of the PMN substance for a commercial purpose. Since polymers which meet the exemption criteria would not be subject to PMN review, they would not be included on the Inventory. Instead, EPA would maintain an independent polymer exemption file. By not being included on the Inventory, exempted polymers will not be considered to be "existing" chemical substances under TSCA. All persons who intend to manufacture or import a polymer under the conditions specified in the exemption criteria would be required to submit an exemption notice, regardless of whether the polymer is already included in the special exemption file. If a manufacturer wishes to manufacture a polymer outside the scope of the proposed exemption criteria, a PMN or other section 5 notice will be required. In the case of a PMN, a polymer is added to the Inventory only upon the receipt of a NOC by EPA. Therefore, it is possible that a given polymer could be listed both in the special polymer exemption file and on the Inventory. Polymers that were reviewed under the 1984 polymer exemption rule and included on the Inventory would remain on the Inventory, with the restrictions concerning low MW species content and maximum residual amounts of reactants specified for each exempted polymer still in force.

15. *Transition period between proposed and final rule.* The Agency will continue to accept polymer exemption notices under the terms of the 1984 exemption at 40 CFR 723.250 until the effective date of any final rule that amends this section. At that time, all exemptions granted by EPA under the terms of the 1984 polymer exemption regulations will remain in effect; however, no new exemptions will be granted under the 1984 polymer exemption rules. Submitters who were granted an exemption under the terms of the 1984 exemption have the option of manufacturing under those terms or of submitting a new exemption notice under the amended regulations.

If an exemption holder continues to follow the 1984 exemption rules, the NOC requirements apply and the exempt polymer will continue to be listed on the Inventory with exclusion criteria, exemption category restrictions, and residual monomer and low MW species content limitations. The exemption holder and any subsequent manufacturers of the polymer must comply with these criteria, or submit a new exemption notice or PMN.

III. Alternatives and Request for Public Comment

EPA requests comments and data on all aspects of this proposal, including provisions of § 723.250 that EPA has proposed to retain unchanged from the 1984 exemption. EPA will consider all comments and data received during the comment period and may amend any provision of § 723.250 where appropriate, based on these comments. Additionally, EPA requests comment on the specific issues and options outlined below.

A. Other Polymers Considered for Exemption

1. *Polymer salts.* The Agency has also considered a proposal to exempt certain salts of polymers that are listed on the TSCA inventory.

During FY 1990, EPA reviewed over 500 PMNs on salts of TSCA Inventory-listed polymers that were submitted by chemical manufacturers. As a result of the Agency's analysis of the health and environmental concerns associated with these polymer salts, EPA determined that in these cases polymer salts generally represented a low hazard, based on structure/activity analysis. In the few cases where potential health and/or environmental concerns were identified in a preliminary review, the Agency determined that the concerns were based on an analysis of the corresponding existing chemical substance (amine or other basic components) used to manufacture the polymer salt, and not on the polymer salt itself. EPA took no action to regulate these salts during the PMN review period. The results of this review support the Agency's view that polymer salts of Inventory-listed polymers as described above, generally present a low risk to health and the environment. Further, Agency concerns associated with the amine or other basic component could be addressed through mechanisms other than requiring new chemical reporting.

The Agency does, however, realize that there exist many polymers listed on the Inventory that have never been subject to the scrutiny of the new chemical substance review. Because of that fact, it is difficult to make the determination that these polymers will not present an unreasonable risk to human health or the environment. It follows, therefore, that the salts of these Inventory listed polymers would have the same uncertainty associated with them. However, EPA believes that many polymer salts would be eligible for exemption under the criteria being proposed in Unit II of this preamble. The Agency invites comments on the treatment of salts of existing polymers as a separate category within the context of this rule.

2. *Other polymers.* EPA considered an option of an expedited 21–day review of all polymers not meeting the exemption criteria which could actually be extended to 90 days if necessary. EPA did not propose this option because these polymers could potentially present significant risk, based on EPA's review of these polymers over the past 10 years. Therefore, these polymers could not be adequately reviewed in the 21–day time frame. EPA believes that a closer examination of the conditions of manufacturing, processing, distribution, use, and disposal during a full 90–day PMN review period is therefore necessary.

B. Notification and Timing of Submission

The Agency considered several options regarding the submission requirements and timing of submission of a polymer exemption application, as discussed below:

1. *No reporting.* The Agency considered an exemption which did not require a manufacturer to notify EPA that a polymer was being manufactured under the exemption, similar to the R&D exemption. As with the exemption for small quantities manufactured solely for R&D at § 720.36, recordkeeping would be required to verify compliance with the exemption criteria. This approach would allow the manufacture of polymers meeting the exemption criteria without the submission of a section 5 PMN or an exemption notice. It would require that manufacturers of such polymers maintain extensive records to verify compliance with the exemption criteria. However, the Agency believes that this approach would eliminate any direct mechanism for monitoring compliance since the Agency would not know the identity of the manufacturer or polymer being produced under the exemption.

2. *Notification on the first day of manufacture.* This option would require that a company submit an abbreviated notice post-marked on the first day of manufacture. The Agency considered this option because it would assure timely reporting, which would aid monitoring and enforcement of the exemption. However, based on comments previously received from the Chemical Manufacturers Association (CMA) on the timing of the NOC, EPA recognizes that requiring notices to be submitted on the same day of

manufacture would be difficult because of "coordination difficulties or the press of other business." (48 FR 41140, September 13, 1983). As stated at that time, EPA believes that companies should be allowed some latitude in when they submit NOCs and that notices submitted a short time after manufacture begins should be accepted. However, under the proposed recordkeeping requirements, EPA believes that under the ambit of the R&D provisions, all information required to support a substance's eligibility under the exemption, including analytical data demonstrating eligibility of § 723.250(e)(1) and (e)(2) polymers, would have to be available prior to first manufacture of an exempted polymer for commercial purposes.

3. *Retention of 21–day premanufacture notification.* As with the current exemption, eligible polymers meeting the exemption criteria would be subject to a 21–day review prior to the commencement of manufacture. EPA believes that such a reporting requirement would require the continuing use of substantial EPA resources to review the data. The Agency believes that this review period is unnecessary, based on EPA's finding that polymers that meet these exemption criteria will not present an unreasonable risk. By not reviewing this category, the Agency can focus its limited resources on those chemicals which pose a significant risk to society. The Agency also considered an option of requiring a 5–day pre-manufacture notification. However, a 5–day period may not provide sufficient time to acknowledge that a submission has been received, raising inquiries from submitters as to official commencement dates.

In order to ensure that companies correctly determine which polymers meet the exemption criteria, the Agency is developing a comprehensive technical support document. This will assist the company to establish that the polymer meets the terms of the exemption.

C. Eligibility Criteria

1. *Functional group equivalent weight.* The Agency also considered the alternative of standardizing the criterion for certain reactive functional groups at § 723.250(e)(1)(ii)(B) at 5,000 equivalent weight instead of establishing both a 1,000 and a 5,000 limit based on the Agency's level of concern. Under the Agency's current internal review policy, polymers with a combined reactive functional group equivalent weight of greater than 5,000 are considered of low concern with respect to both health and environmental effects. While the concern for all of the listed reactive functional groups does not warrant this high 5,000 equivalent weight value, this approach would be a more straight forward threshold for the determination of eligibility for this exemption.

The group-specific values that EPA has proposed, however, correspond much better with the actual levels of concern for the individual reactive functional groups. By employing this method, the Agency feels it allows manufacturers the flexibility of producing more polymers which are of low risk without stringent requirements imposed for the sake of simplicity. The Agency solicits comment on the merits of both approaches. As stated above, the Agency is particularly interested in hearing from small businesses and others about the complicated nature of the first approach.

2. *Residual monomer content.* EPA also considered an option which would have retained the existing requirements that submitters provide such information as number average MW and residual monomer concentration. This requirement would enable EPA to evaluate on a random, periodic basis, information received in support of the certification that a submitter has met the specific exemption criteria for polymers, or to require more information in cases where the Agency may have some specific concerns or questions about the polymer. However, EPA believes that this reporting requirement would complicate the exemption scheme by placing an unnecessary burden on both EPA and submitter resources.

D. Inhalation toxicity

Inhalation concerns for high MW water-insoluble polymers are addressed in the criteria for polymer exemption and EPA is proposing to require that submitters certify that they acknowledge the concerns for inhalation toxicity for some water-insoluble polymers and will employ either worker protection or manufacturing controls to minimize exposure to respirable dust to the extent possible. Several alternatives have also been considered and EPA requests public comment and supporting data on the advantages and detriments of the options. The Agency solicits comments on the following alternatives:

1. *No restrictions on water-insoluble polymers with MW of 10,000 or greater.* EPA considered the alternative of not setting any restrictions on water-insoluble polymers with MW of 10,000 daltons or greater. The data base on polymer inhalation toxicity on water-insoluble polymers is extremely small; therefore it is difficult to characterize a limited data set as representative of all high MW polymers. To impose general regulatory restrictions based on a limited set of very specific data may not be justified. Further, there is a lack of test data on the specific factors which cause the toxicological effect. Without being able to identify the properties of a chemical(s) responsible for the toxic effect, it may be difficult to justify restrictions on the category of high MW polymers. The EPA would like to receive and/or encourage the development of data on the inhalation toxicity of higher MW polymers to establish the generality of the effect and the need for regulatory exposure limits under the polymer exemption.

Therefore, the EPA requests comment on the need to control exposure to water-insoluble polymers with MW of 10,000 daltons or greater in the polymer exemption rule. EPA also requests that any available negative inhalation toxicity data on higher MW polymers be forwarded to the Agency as part of public comment. Of course, persons must submit any positive data indicating "substantial risk" to human health or the environment under TSCA section 8(e).

2. *Promulgate a section 4 test rule for high MW polymers.* EPA considered the alternative of using other TSCA authority, e.g. a section 4 test rule, instead of limiting the exemption. The observed lung toxicity may be a physical effect, which to date, cannot be correlated with chemical-specific characteristics of any class of polymers, except water-absorbable polymers with MW of 1 million daltons or greater. EPA recognizes that PMN occurs on a chemical-specific basis and the lung toxicity caused by respirable dust may not be a chemical-specific phenomenon. Therefore, it is difficult for EPA to define a specific chemical category of concern or an appropriate test battery, at this time.

3. *Exclude polymers from eligibility for exemption if it is reasonably anticipated that there may be inhalation exposure in manufacturing, processing, or use.* Because the data received by EPA on inhalation toxicity are so limited and narrow of scope, and because EPA considered that the concerns could be mitigated by the exemption criteria discussed above, this alternative was considered to be an inappropriate burden relative to the magnitude of the known risk.

EPA requests comments on all alternatives considered in dealing with inhalation concerns along with any supporting data available on inhalation toxicity of polymers.

E. Polymers Containing High Cationic Functional Group

The Agency considered allowing, under the exemption, polymers which contain high percentages of amine (low amine equivalent weight) in their structures that would be restricted at § 723.250(d)(1). The main concern for cationic polymers is for ecotoxicity, specifically, aquatic toxicity. There has been a significant amount of data collected to demonstrate that for the category of polymers with a high amine content, equivalent weight of 425 or less, there is sufficient mitigation of the risk, through the mechanism of humic acid binding, to render this polymer class of low concern for ecotoxicity. The Agency believes that these data sufficiently support the conclusion that high amine content polymers, as specified above, will not pose an environmental risk for aquatic toxicity.

EPA has, however, recently received data, through the provisions of section 8(e) of TSCA, with regard to toxicological studies performed on a polymer with high cationic functional group content. The test results demonstrated lethality in standard eye irritation tests in rabbits and has resulted in concerns for acute lethality as demonstrated by this polymer. The subject polymer met all provisions of the proposed polymer exemption and would have qualified for exemption if the low cationic functional group equivalent weight (high cationic content) provision was incorporated as part of the exemption criteria. It is for this reason that EPA feels that it would be inappropriate to include the high cationic functional group content allowance at this time. EPA is reviewing this category of polymers to attempt to delineate the parameters which may be responsible for this unusual effect. EPA requests any available standard rabbit eye irritation data on these types of polymers. EPA invites comment from the public on this class of polymers and the provisions in this rule for addressing them.

IV. Regulatory Analysis

A. Summary of Risk Assessment

1. *Introduction.* The Agency has decided to expand the applicability of the polymer exemption rule because EPA has determined that many of these substances are of low concern due to their lack of reactivity and their molecular size. The experience gained by the Agency from reviewing over 5,000 polymer submissions since the original polymer exemption rule in 1984 (49 FR 46066) has assisted in formulating the new set of criteria which will define what substances qualify for the polymer exemption. The hazards analysis for this proposed rule provides the evaluation of the information relevant to the Agency's conclusions that (a) polymers eligible for this exemption are generally of low risk and (b) sufficient information exists on the potential toxicity of polymers with certain characteristics to warrant their exclusion from the exemption.

2. *Approach to risk analysis.* The Agency based its risk analysis on (a) the effect MW has on the overall risk a chemical poses, (b) the specific concerns the Agency has had in the past from polymers submitted as PMNs, and (c) toxicological data available on particular chemicals.

The selection of MW as a risk-limiting criterion rests on two well-known and accepted principles of toxicology. The first principle is that, in general, in order to cause an adverse health or ecological effect, a chemical must first be absorbed by the organism. The second is that absorption of a chemical gradually decreases with increasing MW (size). Based on these two principles, the Agency reasoned that potential risks should generally be expected to decrease with increasing MW.

The second risk-limiting criterion is based on historical data gathered by the Agency in the course of reviewing several thousand polymers and identifying the concerns. This historical data gradually evolved into a set of internal Agency criteria for identifying either hazardous or high-risk substances. These internal criteria provide the basis for the proposed polymer exemption requirements that are set forth in this proposal.

3. *Limitations to approach.* The Agency realizes that there are limitations to the general rule that high MW substances will not be readily absorbed and therefore, will be of low concern. It is for these outlying cases that there are exclusions to this proposed exemption for certain polymers that remain subject to PMN. The Agency has reviewed a number of classes of chemicals to assess these risks. An EPA memorandum dated February 1, 1991, which discusses the environmental effects of polymers, is available in the public docket for this document (OPPTS–50594).

4. *Environmental risks.* The Agency has evaluated a large number of polymers for their ecotoxicity in the course of reviewing PMNs. The identified environmental risks have formed the basis for several of the exclusions from the exemption to mitigate these risks. The environmental risk posed by polymers in general can be categorized both by MW characteristics as well as electronic properties. All polymers are divided into four classes depending on the type of electronic charge of the polymer: nonionic (neutral); anionic (negative charge); cationic (positive charge); and amphoteric (mixture of positive and negative charges on same molecule) polymers. The risk these different categories may pose is related both to electronic charge and MW.

a. *Polymers with MW less than 1,000 daltons.* Polymers with a MW of less than 1,000 that possess some degree of water solubility may be of concern. These polymers tend to exhibit much of the same behavior as polymers whose MW is greater than 1,000. These polymers are also of concern due to their potential to be absorbed through biological membranes and cause systemic effects.

b. *Polymers with MW greater than 1,000 daltons.* Polymers with MW greater than 1,000 are only considered a hazard for ecotoxicity when they are water soluble (or self-dispersing). They are not expected to be absorbed through biological membranes, and are expected to assert their toxicity by affecting the outer membranes of aquatic organisms or the near environment of the organism (e.g., over-chelation of nutrient elements). Insoluble polymers are not expected to be toxic unless they are ground up into fine particles. The toxicity of finely ground particles is due to indirect (physical) toxicity (e.g., the clogging of respiratory organs such as gills). Effects of this type only occur at high concentrations, i.e., acute toxicity values of greater than 1000.0 mg/L and chronic toxicity values of greater than 50.0 mg/L. The toxicity of finely ground insoluble polymers does not depend upon the chemical structure of the polymer.

i. *Anionic (negatively charged) polymers.* Polyanionic polymers which have a MW greater than 1,000 and which are water soluble (miscible or self-dispersing) are of concern for aquatic toxicity. Polyanionic polymers are divided into three subclasses: poly(carboxylic acids), poly(aromatic sulfonates), and poly(aliphatic sulfonates).

Poly(carboxylic acids) are of concern only for their toxicity to green algae. Toxicity to algae is moderate with toxicity values ranging from 1 to 100 mg/L (ppm). It appears that the mode of toxic action of these poly(carboxylic acids) is over-chelation of nutrient elements needed by algae for growth. When enough calcium (as divalent cation) is added to a polymer to satisfy

its anionic charges, toxicity to algae is mitigated.

Poly(aromatic sulfonate) polymers with MW greater than 1,000 may be of moderate concern for acute toxicity towards fish and green algae. Polymers in this class have the following characteristic monomers: sulfonated phenols, sulfonated cresols, sulfonated diphenolsulfones, sulfonated diphenyloxides, and sulfonated diphenylsulfones.

Poly(aromatic sulfonate) polymers which have been shown to have low toxicity (i.e., acute toxicity values greater than 100.0 mg/L) or are highly suspected of having low toxicity are composed of the following monomers: benzene sulfonates and sulfonated naphthalene. The Agency does not have enough test data for these polymers to draw any firm conclusions about their toxicity. However, it is suspected that if these polymers show toxicity to aquatic organisms it will be to algae as was observed for the poly(carboxylic acid) polymers.

ii. *Polycationic (positively charged) polymers.* Polycationic polymers include polyamines (primary amines, secondary amines, and tertiary amines); quaternary amines; polysulfoniums; and polyphosphoniums. Polymers which are considered to have the potential for environmental toxicity have MW greater than 1,000 and are water soluble (miscible or self-dispersing). Polymers based on polyglucosamines (i.e., chitosan) are much less toxic than predicted and are no longer of concern.

For polycationic polymers, aquatic toxicity in clean water (i.e., total organic carbon [TOC] < 2 mg/L) increases exponentially with increasing cationic charge density, i.e., protonated and/or quaternarized-N, S or P. Charge density is measured as percent amine-N for nitrogen-based polymers, equivalent weight of N, S, or P, or number of cations per 1,000 MW. Toxicity to aquatic organisms increases exponentially until about 2.5 cations per 1,000 MW (or 3.5 percent amine-nitrogen or an equivalent weight = 400), thereafter, toxicity becomes asymptotic.

5. *Inhalation toxicity.* Health concerns exist for certain types of high MW polymers that have been found to produce lung toxicity if inhaled. The Agency has received several TSCA section 8(e) and other submissions that report irreversible lung damage in experimental animals when respirable size polymer aerosols are inhaled. The data also demonstrated that the onset of the polymer-induced damage may be delayed for as long as 6 months after exposure. Observed toxicity may be a result of "overloading" the clearance mechanisms of the lung; however, at this time the Agency does not have sufficient toxicity data to either confirm or discount the "overload" theory. The Agency does not have sufficient data to determine the precise MW and/or structural considerations that may facilitate the mechanisms causing toxicity, although data received indicate that lung toxicity is produced by certain polymers with MW as low as 70,000 and at respirable concentrations as low as 4 mg/m^3.

The Agency is considering how to deal with potential lung effects in the context of the polymer exemption. Because the 1984 polymer exemption criteria, and the criteria now being considered, are based on structural and compositional characteristics of polymers, it would be difficult or impossible to address concerns for the observed lung effects within the scope of these criteria.

Accordingly, EPA is proposing to require manufactures to provide notice of potential risks and also is proposing a revocation procedure, as described more fully in Unit II of this preamble.

B. Summary of Regulatory Impact Analysis

EPA has evaluated the potential costs of the proposed amendments for potential submitters of section 5 exemption notices. The Agency's complete economic analysis is available in the public record for this proposed rule (OPPTS–50594).

The regulatory impact analysis estimates the costs and benefits attributable to the proposed regulation. In this case, the analysis also contains estimates for the three additional proposed amendments to section 5 regulations that are published elsewhere in this **Federal Register**. These proposals would amend the PMN rule, the Low Volume Exemption Rule, and the Expedited Follow-up rule. As these proposed regulations are amendments to current regulations, the costs and benefits are incremental, estimating the effect of the proposal with respect to the current regulation.

The costs and benefits associated with these proposed amendments are partially quantified; many of the benefits are unquantified but are expected to be of significant importance. Considering only the quantified costs and benefits, there is a cost savings. Since the number of section 5 submissions received by the Agency varies, this analysis used three scenarios, assuming either 1,000, 2,000, or 3,000 annual submissions, to reflect the expected range of submissions. The savings as compared to the current regulation are estimated to be:

Annual Number of Submissions	Annual Cost Savings ($ Million)	
	Industry	Government
1,000	3.7–5.8	1.0–1.3
2,000	7.4–11.2	2.1–2.6
3,000	11.1–16.8	3.1–3.9

The industry costs associated with these amendments are reporting costs, delay costs, and a user fee. Reporting costs are reduced from the current situation due to a reduction in submission requirements. Delay costs, defined as the cost of delayed introduction of the substance into the market due to section 5 regulations, are also reduced due to the elimination of the 21–day pre-manufacture notification requirement. The user fee remains the same. In addition, the amendment makes a larger number of polymers eligible for the exemption, further reducing the reporting and delay costs for those substances.

The unquantified benefits include increased flexibility for industry due to the expanded exemption criteria. The amendments would require workplace controls for those polymers likely to pose a respirable health risk, allowing the submitter to utilize pollution prevention techniques and protect the health of their workers without the delay and effort required for a section 5(e) Order.

C. EPA's Approach to Making the No Unreasonable Risk Finding

1. *Statutory background.* Under section 5(h)(4) of TSCA, EPA is authorized to exempt the manufacturer of any new chemical substance from all or part of the requirements of section 5 if EPA determines that the manufacture, processing, distribution in commerce, use, and disposal of the substance, or any combination of such activities, will not present an unreasonable risk of injury to health or the environment. Section 26(c) of TSCA provides that any action authorized under TSCA for an individual chemical may be taken for a category of such substances.

While TSCA does not contain a definition of "unreasonable risk," the legislative history indicates that the determination of unreasonable risk requires a balancing of the considerations of both the severity and the probability that harm will occur against the effect of the proposed regulatory action on the availability to society of the benefits of the chemical substance [H.R. 1341, 94th Cong., 2nd Session, 14 (1976)]. This analysis can include an estimate of factors such as market potential, the effect of the

regulation on promoting or hindering the economic appeal of a substance, environmental effects, and many other factors which are difficult to define and quantify precisely. EPA must rely not only on data available to it, but also on its professional judgment. Congress recognized that the implementation of the unreasonable risk standard "will vary on the specific regulatory authority which the Administrator seeks to exercise" [Ibid.].

2. *EPA's approach.* In determining whether the category of substances manufactured under the exemption presents an unreasonable risk of injury to human health or the environment, the Agency considers more than just the inherent risks presented by the overall category of polymers. The Agency also considers the extent to which specific, automatic exclusions for polymers having certain characteristics affect the risks as well as the degree to which the development of specific polymeric criteria, have mitigated such potential risks. EPA analyzes to what extent the exemption criteria diminish or address potential risk.

The proposed polymer exemption will modify the requirements for eligible polymers from the current polymer exemption requirements and the general PMN requirements. EPA therefore compares the risks posed by the exemption with the risks which would have resulted from the same category of substances, if that category of substances had been subject to full notice submission requirements and 90–day EPA review or, where applicable, the reporting requirements of the current polymer exemption and the abbreviated 21–day review. Certainly it is not possible to eliminate all risks associated with the manufacture, processing, use, and disposal of a new chemical substance nor was this Congress' intent.

3. *Application of no unreasonable risk factors.* The following is an explanation of the consideration of factors relevant to the no unreasonable risk finding. The design of the proposed polymer exemption together with intrinsic properties of polymers significantly limit the risks of injury to human health or the environment that exempt polymers may present. Polymers as a general class are relatively unreactive and are not easily absorbed by bodily tissue. This proposal would exclude from eligibility, polymers with characteristics which would cast significant doubt on EPA's conclusions regarding low toxicity. EPA's conclusions regarding low toxicity potential for polymers that meet the proposed criteria are supported by the available data as well as EPA's professional judgement gathered over the course of reviewing over 10,000 polymers under the PMN and current polymer exemption requirements.

Under the proposed rule, certain polymers would be automatically ineligible for the polymer exemption. EPA has excluded those polymers for which: (a) The Agency still has insufficient data and review experience to find that they will not present an unreasonable risk, or (b) the Agency has found that, under certain conditions, polymers may present risk, thereby requiring a closer examination of the conditions of manufacturing, processing, distribution, use, and disposal during a full 90–day PMN review. This level of analysis would be necessary to make an appropriate determination about risk.

In 1982, when the Risk Analysis and Evaluation of PMN Regulatory Decisions for Polymers was performed for the original polymer rule, the Agency determined that high MW (MW) polymers containing small amounts of low MW species were not considered an unreasonable risk to humans or the environment. Extensive discussion on this topic can be found in the 1982 proposed polymer exemption rule and the preamble to the final rule promulgated in 1984. The Agency has assumed that monomers would be of greater concern than oligomers, and that oligomers would be of greater concern than polymers based on the probability that the monomer would be more readily absorbed and, on a weight basis, be more reactive than the resulting oligomer or polymer.

In the 1982 proposal, the Agency proposed to allow polymers with MW greater than 20,000 to be manufactured without any premanufacture review by EPA but determined in the final rule that an abbreviated review period was necessary due to concerns for unreacted monomers and low MW species. The Agency is now proposing a modified version of this option, based on the review and hazard assessment of PMN polymers received over the last 7 years. The Agency now believes that it has sufficient experience with high MW polymers such that a "no unreasonable risk" finding may be made for certain of these substances.

As part of its risk assessment and in determining which type of polymer would be the most appropriate subject of an exemption at that time, EPA analyzed its existing database of polymers which had been submitted as full PMNs. Of the 266 polymer PMNs received by the Agency between March 17 and December 31, 1981, 7 were subject to preliminary review and none received formal Agency regulation under section 5(e) or section 5(f) of TSCA. These 266 polymers constitute a significant percentage of the 553 PMNs received during this period. In addition, of the 13 polymer PMNs that would have been eligible for review under the then proposed exemption, 11 were dropped by the Agency after abbreviated review on the basis of chemical/physical property data.

Over the past 13 years, the Agency has reviewed approximately 10,000 polymers in the New Chemicals Program. (Approximately 50 percent of all PMNs are polymers.) Of these 10,000, the majority of the polymers that would have qualified for the proposed polymer exemption rule have consistently been characterized as posing low concern for both adverse health and environmental effects by the Agency. The characteristics of a significant number of polymers are such that they are either not absorbed by biological systems or do not interact with biological systems. Furthermore, these polymers do not degrade to toxic species in the environment. However, based on data received by the Agency and referenced above, there is a second category of polymers which may pose a risk which the Agency believes can nonetheless be controlled through the use of process changes, engineering controls or use of personal protective equipment.

As a class, the Agency considers polymers to be among the safest chemical substances known. Based on over 13 years experience with the review and evaluation of new polymers, the Agency has established specific criteria which define low-risk polymeric substances. For example, the low MW species, reactive functional group, and the cationic limitations serve as such criteria. Many of these proposed criteria are outgrowths of the criteria used to determine eligibility under the current polymer exemption that has been in effect since 1984. Further, the Agency uses these identical criteria to identify low-risk polymers in its PMN review process.

The current polymer exemption, which uses the same types of criteria as the proposed exemption criteria to determine eligibility, requires a 21–day review period. The Agency believes that this review period for polymers that meet the proposed exemption criteria is unnecessary based on EPA's finding that polymers which meet these exemption criteria put a sufficient bound on risk so that EPA review would not result in any additional protection. As a result, the Agency can then refocus its limited

resources from this category of low risk concerns to those chemicals which, by comparison, may pose a considerable risk to society. Of the 1,371 polymers reviewed under the existing polymer exemption, only 1 polymer raised a concern of unreasonable risk based on ecotoxicity concern for significant releases; however, the case was dropped from review after receipt of algal test results which mitigated the Agency's concerns.

To further characterize the risk of the polymers that would be eligible for the proposed polymer exemption, the database of TSCA section 8(e)/FYI submissions was reviewed. Section 8(e) of TSCA requires that information on chemical substances which present a substantial risk of injury to human health or the environment be submitted to the Agency. A review of approximately 1,300 section 8(e) submissions revealed that, while polymers were the subject of 72 submissions, only 4 of the chemical substances identified in these 8(e) submissions would have been eligible for today's proposed polymer exemption (assuming the proposed worker protection provisions were not taken into consideration). The remaining 68 would be excluded from the proposed exemption due to MW considerations, restricted constituents and/or an excess amount below the MW of 500 or 1,000.

As discussed in Unit II of this preamble, the data received by the Agency on the six referenced submissions indicate that inhalation of respirable particles of certain of these polymers resulted in irreversible lung damage to experimental animals. In response to these new data, the Agency convened a Workshop to analyze the data to characterize the toxicity and chemical structures which may be responsible for the reported toxicity. The proceedings of the workshop are available in the Public Docket at OPPTS–50594.

Based on the small size of this data set and the uncertainty of the cause of identified effects, the Agency is not willing at this time to draw any broad scientific conclusions for a class of compounds that numbers well over the 30,000 currently listed on the TSCA Inventory. As discussed in Unit II of this preamble, the Agency is proposing to exclude from the exemption, polymers having MW of 10,000 daltons or greater that are water-absorbing in response to TSCA section 8(e) data received by EPA. In addition, under the proposal, procedural safeguards to control inhalation exposure would be imposed on water-insoluble polymers having MW of 10,000 or greater if there is a potential for inhalation exposure to respirable particles. Chemicals other than these polymers which cause similar effects are generally insoluble particles of inorganic materials, such as titanium dioxide, which have no obvious chemical similarity to the subject polymers. However, if there is a potential for inhalation exposure to any respirable particles of water-insoluble polymers of MW greater than or equal to 10,000 daltons, the Agency believes it cannot make an affirmative finding that the activities associated with eligible polymers will not present an unreasonable risk of injury to human health and the environment unless respiratory protection or other workplace controls are used.

4. *Mitigation of potential risks.* In order to mitigate potential risks if the potential for inhalation exposure exists, the Agency has determined that: (a) By requiring manufacturers and importers to notify persons in its employ of the potential inhalation toxicity of respirable particles; (b) by requiring exposed workers to use respirators in accordance with applicable OSHA and National Institute for Occupational Safety and Health (NIOSH) requirements, or, in the alternative, by maintaining a specified workplace inhalation exposure level; (c) by requiring subsequent risk notification to processors and industrial users; (d) inclusion of strong revocation procedures; and (e) by the exclusions and terms of the exemption itself, the "no unreasonable risk" finding can in fact be made on a classwide basis for purposes of this exemption. These provisions are more fully described in Unit II of this preamble. The Agency believes that the exclusions and conditions are sufficient to mitigate risk, particularly when compared to the benefits, in toto, of encouraging further development of comparatively lower risk classes of chemicals with significant consumer exposure, such as polymers.

Because of the safeguards in the proposed rule, the requirement that the information provided in submissions are binding on the submitter, and the restricted nature of the exemption categories, EPA believes that risks are not likely to be any greater than if PMNs are filed and reviewed by EPA. Furthermore, the new polymers provide benefits to industry and to the public, which comprise an important element in the finding of no unreasonable risk.

In addition to the exclusions described in the proposed rule, the Agency in § 723.250(e)(2) is proposing the adoption of notification requirements which are similar to provisions in the R&D exemption at § 720.36(c) if there is potential inhalation exposure to respirable particles of high MW water-insoluble polymers. These would include notification of risks related to inhalation concerns raised by section 8(e) data, by the manufacturer of the exempt polymer [see 40 CFR 720.36 and 720.78]. The rule would require manufacturers to evaluate information which would lead the manufacturer to believe there is a potential risk of inhalation exposure to the substance based on respirable particulates, and would require the manufacturer to notify employees and persons to whom the polymer is distributed of any risk identified during the review. Such notification would help to address the concerns raised by the section 8(e) data which indicated irreversible lung damage in experimental animals.

At the present time, a 2–year chronic inhalation bioassay would be recommended to fully evaluate the potential for lung toxicity from exposure to high MW polymers. The Agency encourages manufacturers and importers to develop and conduct appropriate toxicity testing to determine the lung toxicity from inhalation exposure to respirable polymer dusts. The docket for the proposed rule details the concerns for inhalation toxicity and raises awareness regarding the potential inhalation risks associated with certain polymers. The Agency is attempting to address the concerns raised by the section 8(e) data regarding inhalation toxicity in the proposed rule and in the PMN program. If EPA determines in the future that concerns for these polymers are mitigated or modified, it will consider revising the exemption to either delete or modify the workplace control limitations currently in the proposed rule, as appropriate, and consistent with its statutory mandate to make a "no unreasonable risk" finding.

The Agency believes that notification through labeling; notice where actual exposure is expected to occur; individual written notice or use of any other method which adequately informs persons of potential inhalation risk which EPA has reason to believe may be associated with the substance; will mitigate risk to potentially exposed populations, thereby enabling EPA to make the necessary no unreasonable risk finding.

Despite the low risk generally associated with the types of polymers that would qualify for this exemption, EPA recognizes that as the scientific community, and EPA, gain a better understanding of these substances and the potential risks associated with them,

new risks may be identified. Although EPA does not currently have any information indicating that any particular polymers or categories of polymers that meet the proposed criteria for this exemption may present an unreasonable risk, it is possible that in the future EPA will obtain such information. To minimize any potential risks posed by this exemption, EPA is proposing a provision in this polymer exemption rule that would enable EPA to revoke exemptions where EPA obtains information indicating that a particular polymer or category of polymers may present an unreasonable risk of injury to health or the environment.

The Agency has proposed revocation language in the polymer exemption which would allow EPA to revoke the exemption for an exempted polymer and require a full PMN review, should the Agency obtain new information that identifies a hazard that results in a "may present" an unreasonable risk finding. Such a determination could be based on any new information, or when the body of toxicity data permits a sound scientific judgment regarding the mechanisms of lung toxicity or the structural guidelines for the toxicity referenced above.

If a polymer were eligible for the proposed polymer exemption, the polymer would not be listed on the Inventory, thereby precluding manufacture by any one other than the company submitting the exemption notice. Furthermore, based on information received on the substance itself, or analog data, the exemption status could be revoked at any time if information becomes available which results in a finding that the polymer may present an unreasonable risk to human health or the environment.

5. *Benefits.* The following discussion describes the benefits of this proposal in a qualitative manner; for a more quantitative approach, see the economic analysis discussion in Unit IV.B of this preamble. It is reasonable to assume that a newly developed polymer will either possess a new function or serve an existing function more efficiently or less expensively. The reduction in delay for that polymer to be introduced into commerce is a benefit to both manufacturers and the general public, who will have access to the substance in a more timely manner.

A consideration of which benefits to analyze would encompass more than the costs associated with or from having to submit the polymer as a full PMN. Rather, any benefit analysis undertaken by the Agency would include a consideration of the broader benefits of reduction of costs to society by providing a less burdensome alternative for polymer manufacturers, including a reduction in the burden associated with both full PMN and current polymer exemption requirements. EPA's unreasonable risk determination may be based on the effects from provision of the substances on society beyond those benefits attributable to the substance itself.

Some of the costs directly attributable to the substance include the preparation of the PMN or polymer exemption form as well as the delay in the commercial market introduction of the new chemical substance. On the other hand, there are broad societal benefits which are not directly attributable to any one chemical substance or category of substances. Such benefits would include a reduction in Agency review resources being dedicated to a category of compounds determined to be of low risk, and a concomitant shift in concentration of those resources to substances of greater known concern. While factors such as these are not of the type that EPA would take into account when making an individual control decision on a new chemical substance, they have a significant effect on society which is directly linked to EPA's exercise of its exemption authority, and are appropriately considered in a section 5(h)(4) unreasonable risk finding for a category of substances. The costs of reporting requirements will also be lessened due to the limited informational requirements imposed under the proposed polymer exemption. These savings are detailed in the Regulatory Impact Analysis report which is available in the public docket for this rulemaking (docket control number OPPTS–50594).

In addition, if the exemption is used to its greatest advantage, more than 31 percent of the resources allocated to the PMN burden could be shifted from this category of low concern to those chemicals which are considered to pose a considerably greater risk to society by comparison. Finally, manufacturers of these polymeric substances will be given greater flexibility provided they meet the terms of the criteria of the exemption.

In view of the expansive and continually increasing use of polymers in commerce, encouraging industry to expand the use of low hazard polymers can result in significant benefits to society. In general, such low hazard polymers function as replacements for heavy metals, many of which can cause detrimental human health effects to multiple organ systems as well as permanently contaminating the ecosystem with subsequent damage to the flora and fauna. The benefit of encouraging low hazard chemical substances in place of known hazards touch on all aspects of human activity and the environment including less hazardous work place environments, safer products available for the consumer, and materials that will not decompose to toxic products in the disposal sites. Such benefits outweigh risks which may be associated with inhalation of an as yet undefined subset of polymers, taking into consideration the exposure controls included in this proposal.

6. *Risk/benefit balance.* Determining the presence or absence of an unreasonable risk requires balancing of the benefits and risks posed by a regulatory action. EPA has determined that the risks are low based on the inherent properties of this class of substances; the additional safeguards built into the eligibility criteria; and the exposure controls included to mitigate any risks. EPA, of course recognizes its authority to revoke any exemption when and if information becomes available to it which would warrant such action.

EPA believes that the benefits of this proposed action are quite significant. Promoting the development of this category of polymeric substances by reducing the regulatory burden in both reporting requirements and in eliminating the delay of these products into commerce will have clear benefits to society. The added benefit of concentrating limited resources on substances which have a greater potential to present significant risks rather than a category such as polymers which have a minimal potential for significant risk is difficult to quantify, but is considered substantial nonetheless.

Given the above analysis, EPA concludes that the polymers covered by the proposed revision of the polymer exemption rule will not present an unreasonable risk of injury to human health or the environment.

V. Comments Containing Confidential Business Information

Any person who submits comments claimed as confidential business information must mark the comments as "confidential," "trade secret," or other appropriate designation. Comments not claimed as confidential at the time of submission will be placed in the public file. Any comments marked as confidential will be treated in accordance with the procedures in 40 CFR part 2. Any party submitting comments claimed to be confidential

must prepare and submit a nonconfidential public version in triplicate of the comments that EPA can place in the public file.

VI. Rulemaking Record

EPA has established a record for this rulemaking (docket control number OPPTS–50594). The record includes basic information considered by the Agency in developing this proposed rule. A public version of the record without any confidential information is available in the TSCA Public Docket Office from 8 a.m. to 12 noon and 1 p.m. to 4 p.m., Monday through Friday, except legal holidays. The TSCA Public Docket Office is located at EPA Headquarters in Rm. NE–G004, 401 M St., SW., Washington, DC.

VII. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "major" and therefore requires a Regulatory Impact Analysis. EPA has determined that this rule would not be a "major" rule because it would not have an effect on the economy of $100 million or more, and it would not have a significant effect on competition, costs, or prices.

This proposed regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), EPA has determined that this rule would not have a significant impact on a substantial number of small businesses. EPA has not determined whether parties affected by this rule would likely be small businesses. However, EPA believes that the number of small businesses affected by this rule would not be substantial, even if all of the polymer exception notice submitters were small firms. They will have reduced burdens compared to the PMN process and the existing exemption.

C. Paperwork Reduction Act

The information collection requirements in this rule have been approved under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3502 et. seq. and have been assigned OMB control number 2070–0012.

The public reporting burden for this collection of information is estimated to vary from 10 to 14 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The public reporting burden for a PMN submission is estimated to vary from 95 to 110 hours; the burden for the 1984 polymer exemption is estimated to vary from 29.5 to 40 hours.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Chief, Information Policy Branch, PM–223, U.S. Environmental Protection Agency, 401 M. St., SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

List of Subjects in 40 CFR Part 723

Chemicals, Environmental protection, Hazardous materials, Premanufacture notification, Reporting and recordkeeping requirements.

Dated: January 19, 1993.

William K. Reilly,
Administrator.

Therefore, 40 CFR chapter I, subchapter R, part 723 is proposed to be amended as follows:

PART 723—[AMENDED]

1. The authority citation for part 723 would continue to read as follows:

Authority: 15 U.S.C. 2604

2. By revising § 723.250 to read as follows:

§ 723.250 Polymers.

(a) *Purpose and scope.* (1) This section grants an exemption from certain of the premanufacture notice requirements of section 5(a)(1)(A) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture of certain polymers.

(2) To manufacture a new chemical substance under the terms of this section, a manufacturer must:

(i) Determine that the substance meets the definition of polymer in paragraph (b) of this section.

(ii) Determine that the substance is not specifically excluded by paragraph (d) of this section.

(iii) Ensure that the substance meets the exemption criteria of paragraph (e) of this section.

(iv) Submit a notice as required under paragraph (f) of this section.

(v) Comply with the recordkeeping requirements of paragraph (l) of this section.

(b) *Definitions.* In addition to the definitions under section 3 of the Act, 15 U.S.C. 2602, the following definitions apply to this part.

Act means the Toxic Substances Control Act (115 U.S.C. 2601 et seq.).

Biopolymer means a polymer directly produced by living or once-living cells or cellular components.

Category of chemical substances has the same meaning as in section 26(c)(2) of the Act (15 U.S.C. 2625).

Cationic polymer means a polymer that contains a net positively charged atom(s) or associated groups of atoms covalently linked to its polymer molecule.

Chemical substance, Director, EPA, importer, impurity, Inventory, known to or reasonably ascertainable, manufacture, manufacturer, mixture, new chemical, person, possession or control, process and test data have the same meanings as in § 720.3 of this chapter.

Internal monomer unit means a monomer unit that is covalently bonded to at least two other monomer units. Internal monomer units of polymer molecules are chemically derived from monomer molecules that have formed covalent bonds between two or more other monomer molecules.

Monomer means a chemical substance that has the capacity to form chemical bonds between two or more other molecules.

Monomer Unit means the reacted form of the monomer in a polymer bonded to two or more other molecules.

Number-average molecular weight means the arithmetic average (mean) of the molecular weight of all molecules in a polymer.

Polyester means a chemical substance that meets the definition of polymer and whose polymer molecules contain at least two carboxylic acid ester linkages, at least one of which links internal monomer units together.

Polymer means a chemical substance consisting of molecules characterized by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least 3 monomer units which are covalently bound to at least one other monomer unit or other reactant and which consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units.

Polymer molecule means a molecule which includes at least 3 covalently bound monomer units; at least two of which are internal monomer units.

Reactant means a chemical substance that is used intentionally in the manufacture of a polymer to become

chemically a part of the polymer composition.

Reactive functional group means an atom or associated group of atoms in a chemical substance that is intended or can reasonably be anticipated to undergo facile chemical reaction.

Reasonably anticipated means that a knowledgeable person would expect a given physical or chemical composition or characteristic to occur based on such factors as the nature of the precursors used to manufacture the polymer, the type of reaction, the type of manufacturing process, the products produced in polymerization, the intended uses of the substance, or associated use conditions.

(c) *Applicability.* This section applies to manufacturers of new chemical substances that otherwise must submit a premanufacture notice to EPA under § 720.22 of this chapter. New substances are eligible for exemption under this section if they meet the definition of "polymer" in paragraph (b) of this section, and the criteria in paragraph (e) of this section, and if they are not excluded from the exemption under paragraph (d) of this section.

(d) *Polymers that cannot be manufactured under this section*— (1) *Cationic polymers.* A polymer cannot be manufactured under this section if the polymer is a cationic polymer as defined under paragraph (b) of this section or if the polymer is reasonably anticipated to become a cationic polymer in a natural aquatic environment (e.g., rivers, lakes) unless:

(i) The polymer is a solid material that is not soluble or dispersible in water and will be used only in the solid phase (for example, polymers that will be used as ion exchange beads), or

(ii) The combined functional group equivalent weight of cationic groups in the polymer is equal to or greater than 5,000.

(2) *Elemental limitations.* (i) A polymer manufactured under this section must contain as an integral part of its composition at least two of the atomic elements carbon, hydrogen, nitrogen, oxygen, silicon, and sulfur.

(ii) A polymer cannot be manufactured under this section if it contains as an integral part of its composition, except as impurities, any elements other than the following:

(A) The elements listed in paragraph (d)(2)(i) of this section.

(B) Sodium, magnesium, aluminum, potassium, calcium, chlorine, bromine, and iodine as the monatomic counterions Na+, Mg+2, Al+3, K+, Ca+2, Cl-, Br-, or I-.

(C) Fluorine, chlorine, bromine, and iodine covalently bound to carbon.

(D) Less than 0.20 weight percent of any combination of the atomic elements lithium, boron, phosphorus, titanium, manganese, iron, nickel, copper, zinc, tin, and zirconium.

(3) *Polymers which degrade, decompose, or depolymerize.* A polymer cannot be manufactured under this section if the polymer is designed or is reasonably anticipated to substantially degrade, decompose, or depolymerize.

(4) *Polymers manufactured or imported from monomers and reactants not on the TSCA Chemical Substance Inventory.* A polymer cannot be manufactured under this section if the polymer being manufactured or imported comprises monomers and/or other reactants not already included on the TSCA Chemical Substance Inventory.

(5) *Water absorbing polymers with number average molecular weight (MW) 10,000 and greater.* A polymer cannot be manufactured under this section if the polymer being manufactured or imported is considered a water absorbing polymer and has a number average MW greater than or equal to 10,000. A water-absorbing polymer is a polymeric substance that, either in whole or in part, increases its volume when in contact with water. A polymer that is partially water soluble and partially water-absorbing shall be considered water-absorbing for the purposes of this section.

(e) *Exemption criteria.* To be manufactured under this section, the polymer must meet one of the following criteria:

(1) *Polymers with number average MW greater than or equal to 1,000 and less than 10,000 (and oligomer content less than 10 percent below MW 500 and less than 25 percent below MW 1,000).* (i) The polymer must have a number average MW greater than or equal to 1,000 and less than 10,000 and contain less than 10 percent oligomeric material below MW 500 and less than 25 percent oligomeric material below MW 1,000.

(ii) A polymer cannot be manufactured under this paragraph if the polymer contains reactive functional groups that are intended or reasonably anticipated to undergo further reaction unless it meets one of the following criteria:

(A) The polymer contains no or only the following reactive functional groups: carboxylic acid groups, aliphatic hydroxyl groups, unconjugated olefinic groups that are considered "ordinary", butenedioic acid groups, those conjugated olefinic groups contained in naturally-occurring fats, oils, and carboxylic acids, blocked isocyanates (including ketoxime-blocked isocyanates), thiols, unconjugated nitrile groups, and halogens (except that reactive halogen-containing groups such as benzylic or allylic halides would not be included).

(B) The polymer has a combined reactive group equivalent weight greater than or equal to 1,000 for the following reactive functional groups: acid halides; acid anhydrides; aldehydes, hemiacetals; methylolamides, - amines or, - ureas; < C2 alkoxysilanes; allyl ethers; conjugated olefins; cyanates; epoxides; imines; or unsubstituted positions *ortho* or *para* to phenolic hydroxyl.

(C) If any reactive functional groups not included in paragraph (e)(1)(ii)(A) or (B) of this section are present, the combined reactive group equivalent weight, including any groups listed in paragraph (e)(1)(ii)(B), must be greater than or equal to 5,000.

(2) *Polymers with number average MW greater than or equal to 10,000 (and oligomer content less than 2 percent below MW 500 and less than 5 percent below MW 1,000).* The polymer must have a number average MW greater than or equal to 10,000 and contain less than 2 percent oligomeric material below MW 500 and less than 5 percent oligomeric material below MW 1000. In addition, for all water insoluble polymers greater than or equal to 10,000 MW to be manufactured under the terms of this section, the manufacturer must:

(i) Notify persons in its employ of the following if there is a potential for their inhalation exposure to any respirable particulates of the substance as identified under paragraph (e)(2)(ii) of this section:

(A) The potential for harmful lung effects upon inhalation of respirable particulates of the substance.

(B) The requirements of paragraph (e)(2)(iv) of this section. The notification must be in accordance with paragraph (e)(2)(iii) of this section.

(ii) Evaluate the potential for inhalation exposure to any respirable particulates of this substance.

(iii) Notify each person in its employ that may be potentially exposed to any respirable particulates of this substance by means of a container labeling system, conspicuous placement of notices in areas where exposure may occur, written notification, or any other form of notification which adequately informs persons of the potential inhalation exposure as determined under paragraph (e)(2)(ii) of this section, the potential for harmful lung effects upon inhalation of respirable particulates of the substance, and the requirements of paragraph (e)(2)(iv) of this section.

(iv) Provide to, and require to wear, each person in its employ that may be potentially exposed to any respirable particulates of the substance the following respiratory protection:

(A) At a minimum, a Category 21C or 23C respirator equipped with a high efficiency filter, selected in accordance with the National Institute for Occupational Safety and Health (NIOSH) Respirator Decision Logic (DHHS/NIOSH Publication No. 87–108 or current version) and used in accordance with 29 CFR 1910.134 and 30 CFR part 11. Respirators shall be selected such that employee exposure to respirable dust, mist, or aerosol of this substance via inhalation does not exceed 0.5 mg/m^3 in any 8–hour work shift of a 40–hour work week.

(B) Employees are not required to wear respirators if alternate controls in the workplace are provided so that inhalation exposure to respirable dust, mist, or aerosol of the new chemical substance in the workplace during manufacture, processing, and use does not exceed 0.5 mg/m^3 in any 8–hour work shift of a 40–hour work week. Process changes, work practices, good housekeeping, and maintenance practices can effectively reduce exposure to airborne respirable polymer materials. Examples of process changes that can reduce exposure include using the substance in solution, in pellet form, or as a wet cake. Application methods other than spray applications that can reduce airborne respirable exposures include roller coating, dip coating, etc. Good housekeeping may include such practices as wet mopping or vacuuming spills instead of dry sweeping and the repair of leaks as soon as possible.

(v) Provide in writing to processors and industrial users to whom it directly distributes the polymer a notice of potential inhalation exposure to any respirable particulates of the substance if such a determination is made in accordance with paragraph (e)(2)(ii) of this section and the potential for harmful lung effects upon inhalation of respirable particulates of the substance. The manufacturer must also inform processors and industrial users of respirator or alternate workplace controls specified in paragraph (e)(2)(iv) of this section so that inhalation exposure to respirable dust, mist, or aerosol of the new substance in the workplace during processing or use does not exceed 0.5 mg/m^3 in any 8–hour work shift of a 40–hour work week. The manufacturer may notify processors and industrial users by means of a container labeling system, written notification, material safety data sheet, or any other method that adequately informs them of inhalation exposure potential to any respirable particulates of the substance, the potential for harmful lung effects upon exposure to respirable particulates of the substance, and the use of respirator or alternate workplace controls. If the manufacturer learns that a customer is processing or using the substance in violation of prescribed respirator or alternate workplace controls, the manufacturer must cease distribution of the substance to the customer immediately. The manufacturer must also report this action to EPA within 15 working days of receipt of this information under paragraph (i) of this section.

(3) *Polyester polymers.* The polymer is a polyester as defined in paragraph (b) of this section and is manufactured solely from one or more of the reactants in the following Table 1:

TABLE 1.— LIST OF REACTANTS FROM WHICH POLYESTER MAY BE MADE

Reactant	CAS No.
Monobasic Acids and Natural Oils	
Benzoic acid	65–85–0
Coconut oil	[1]8001–31–8
Corn oil	[1]8001–30–7
Cottonseed oil	[1]8001–29–4
Dodecanoic acid	143–07–7
Fatty acids, coco	[1]61788–47–4
Fatty acids, linseed oil	[1]68424–45–3
Fatty acids, safflower oil	
Fatty acids, soya	[1]68308–53–2
Fatty acids, sunflower oil	[1]84625–38–7
Fatty acids, tall-oil	[1]61790–12–3
Fatty acids, tall-oil, conjugated	
Fatty acids, vegetable oil	[1]61788–66–7
Heptanoic acid	111–14–8
Hexanoic acid	142–62–1
Hexanoic acid, 3,3,5-trimethyl-	3302–10–1
Linseed oil	[1]8001–26–1
Nonanoic acid	112–05–0
Oils, Cannabis	
Oils, anchovy	
Oils, babassu palm	
Oils, herring	[1]68153–06–0
Oils, menhaden	[1]8002–50–4
Oils, olticica	[1]8016–35–1
Oils, palm kernel	[1]8023–79–8
Oils, perilla	[1]68132–21–8
Oils, walnut	[1]8024–09–7
Oils, sardine	
Safflower oil	[1]8001–23–8
Soybean oil	[1]8001–22–7
Sunflower oil	[1]8001–21–6
Tung oil	[1]8001–20–5
Di and Tri Basic Acids:.	
1,2-Benzenedicarboxylic acid	88–99–3
1,3-Benzenedicarboxylic acid	121–91–5
1,4-Benzenedicarboxylic acid	100–21–0
1,2,4-Benzenetricarboxylic acid	528–44–9
Butanedioic acid	110–15–6
2-Butenedioic acid (E)	110–17–8

TABLE 1.— LIST OF REACTANTS FROM WHICH POLYESTER MAY BE MADE—Continued

Reactant	CAS No.
Decanedioic acid	111-20-6
Hexanedioic acid	124-04-9
Nonanedioic acid	123-99-9
Polyols	
1,3-Butanediol	107-88-0
1,4-Butanediol	110-63-4
1,4-Cyclohexanedimethanol	105-08-8
1,2-Ethanediol	107-21-1
1,6-Hexanediol	629-11-8
1,3-Pentanediol, 2,2,4-trimethyl-	144-19-4
1,2-Propanediol,	57-55-6
1,3-Propanediol, 2,2-bis(hydroxymethyl)-	115-77-5
1,3-Propanediol, 2,2-dimethyl-	126-30-7
1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-	77-99-6
1,3-Propanediol, 2-(hydroxymethyl)-2-methyl-	77-85-0
1,2,3-Propanetriol	56-81-5
1,2,3-Propanetriol, homopolymer	25618-55-7
2-Propen-1-ol, polymer with ethenylbenzene	25119-62-4
Modifiers	
Acetic acid, 2,2'-oxybis-	110-99-6
1-Butanol	[2]71-36-3
Cyclohexanol	108-93-0
Cyclohexanol, 4,4-(1-methylethylidene)bis-	80-04-6
Ethanol, 2-(2-butoxyethoxy)-	112-34-5
1-Hexanol	111-27-3
Methanol, hydrolysis products with trichlorohexylsilane and trichlorophenylsilane	[1]72318-84-4
1-Phenanthrenemethanol, tetradecahydro-1,4a-dimethyl-7- (1-methylethyl)-	13393-93-6
Phenol, 4,4'-(1-methylethylidene)bis, polymer with 2,2'- [(1-methylethylidene)bis(4,1-phenyleneoxymethylene)] bis[oxirane]	25036-25-3
Siloxanes and Silicones, di-Me, di-Ph, polymers with Ph silsesquioxanes, methoxy-terminated	[1]68440-65-3
Siloxanes and Silicones, di-Me, methoxy Ph, polymers with Ph silsesquioxanes, methoxy-terminated	[1]68957-04-0
Siloxanes and Silicones, Me Ph, methoxy Ph, polymers with Ph silsesquioxanes, methoxy- and Ph-terminated	[1]68957-08-2
Silsesquioxanes, Ph Pr	[1]68037-90-1

[1] Chemical substance of unknown or variable composition, complex reaction products, and biological materials (UVCB). The CAS Registry Numbers for UVCB substances are not used in CHEMICAL ABSTRACTS and its indexes.
[2] These substances may not be used in a substance manufactured from fumaric or maleic acid because of potential risks associated with esters, which may be formed by reaction of these reactants.

(f) *Exemption notice.* An exemption notice must be submitted to EPA no later than 30 days after commencement of manufacture for commercial purposes.

(1) *Notice form.* The information set forth in paragraph (f)(2) of this section must be submitted on EPA Form No.7710-?? (Form number to be assigned) as identified below.

(2) *Contents of exemption notice.* For substances exempt under paragraph (e) of this section the notice must include to the extent known to or reasonably ascertainable by the manufacturer:

(i) *Manufacturer's name.* This includes the name and address of the manufacturer and the name and telephone number of a technical contact in the United States.

(ii) *Type of exemption.* A designation on page 1 of the notice, of whether the manufacturer is claiming an exemption under paragraph (e)(1), (e)(2), or (e)(3) of this section.

(iii) *Site of manufacture.* The name and street address of the site of first manufacture or import.

(iv) *Chemical identity information.* (A) The identity by specific chemical name and CAS Registry Number (or EPA assigned Accession Number) of each "reactant", as that term is defined in paragraph (b) of this section, used at greater than two weight percent in the manufacture of the polymer. The manufacturer may determine whether a reactant is used at greater than two weight percent according to either the weight of the reactant charged to the reaction vessel or the weight of the chemically combined (incorporated) reactant in the polymer. Manufacturers who choose the "incorporated" method must maintain analytical data to demonstrate compliance with this paragraph.

(B) A representative structural diagram, as complete as can be known, of the polymer.

(C) The currently correct Chemical Abstracts (CA) Index name for the polymeric substance or the CA preferred name (whichever is appropriate based on Chemical Abstract Service (CAS) 9th Collective Index nomenclature rules and conventions).

(D) The currently correct CAS Registry Number (CASRN) for the polymeric substance if a CASRN already exists for the substance in the CAS Registry File.

(v) *Generic chemical identity.* If the chemical identity provided under this section is claimed as confidential information under paragraph (h) of this section, the notice must provide a non-confidential description of this information which is only as generic as necessary to protect the confidentiality of the information.

(vi) *Test data and other data.* Test data on the polymer in the possession or control of the manufacturer, a description of other data concerning the health and environmental effects of the polymer that are known to or reasonably ascertainable by the manufacturer, and a description of data on related chemicals, as required in § 720.50 of this chapter. (Identify as an attachment to the notice.)

(vii) *Date of first manufacture or import.* The date of first manufacture or import of the substance under the terms of this exemption.

(viii) *Certification.* A certification that:

(A) The notice includes all test data and other data required.

(B) The person submitting the notice manufactured or imported the polymer for a commercial purpose other than for research and development.

(C) All information provided in the notice is complete and truthful as of the date of submission.

(D) The new chemical substance meets the definition of a polymer, is not

specifically excluded from the exemption, and meets the conditions of the exemption. (Certification on page 1 of exemption form, plus the statement required by paragraph (f)(2)(viii)(D) of this section.)

(E) The person submitting the notice for a water insoluble polymer with a number average MW of 10,000 or greater (and oligomer content less than 2 percent below MW 500 and less than 5 percent below MW 1,000) is aware of the potential for harmful lung effects upon inhalation of respirable particulates of certain high molecular weight polymers as described in this chapter and has complied with paragraph (e)(2) of this section.

(F) The person submitting the notice is providing a correct chemical identification of this substance using Chemical Abstract Services (CAS) nomenclature as required under paragraph (f)(2)(iv) of this section.

(G) The Company named in Part 1 of the form has remitted the fee specified at 40 CFR 700.45(b) or, the Company named in Part 1 of the form is a small business concern under 40 CFR 700.43 and has remitted a fee of $100 in accordance with 40 CFR 700.45(b).

(ix) *List of attachments.* The notice must include a list of attachments submitted with the notice.

(g) *Notice procedures.* The following sections of 40 CFR part 720 of this chapter apply to the handling of notices under this section.

(1) Section 720.25 Determining whether a chemical substance is on the Inventory.

(2) Section 720.40 General. (Notice Form, paragraphs (g) and (h).

(3) Section 720.57 Imports.

(4) Section 720.70 Notice in the Federal Register.

(5) Section 720.80 General Provisions.

(6) Section 720.90 Data from health and safety studies.

(7) Section 720.95 Public file.

(h) *Confidentiality.* (1) If the manufacturer submits to EPA under this section information which it claims as confidential business information, the manufacturer must clearly identify the information at the time of submission to EPA in the manner prescribed on the notice form or by bracketing and stamping "CONFIDENTIAL" any attachment. Any information so identified will be treated in accordance with the procedures in part 2 of this chapter. Any information not claimed confidential at the time of submission may be made available to the public without further notice. A submitter may assert a claim of confidentiality for the chemical identity only if the submitter believes that public disclosure of the fact that anyone manufactures or imports the new chemical substance for commercial purposes would reveal confidential business information.

(2)(i) Any person who asserts a claim of confidentiality for chemical identity under this paragraph must provide a generic name that is only as generic as necessary to protect the confidential chemical identity of the particular chemical substance. The name should reveal the specific chemical identity to the maximum extent possible.

(ii) The generic name provided by the submitter will be subject to EPA review and approval in accordance with the procedures specified in § 720.85(b)(6) of this chapter. The generic name provided by the submitter or an alternative selected by the EPA under these procedures will be placed on a public list of substances exempt under this section.

(3) If any information is claimed confidential, the manufacturer must submit a second copy of the notice except that all information claimed as confidential in the first copy must be deleted. EPA will place the second copy in the public file.

(i) *Additional information.* If the manufacturer of a new chemical substance under the terms of this exemption obtains test data or other information indicating that the new chemical substance may not qualify for the exemption, the manufacturer must submit these data or information to EPA within 15 working days of receipt of the information.

(j) *Notification of receipt of notice.* EPA will file for publication with the Office of the Federal Register, a notice of receipt by means of paragraph (g)(4) of this section. This notice does not constitute a finding by EPA that the notice, as submitted, is in compliance with this section. EPA will consider a person to have submitted the notice on the date the notice is received by the Document Control Officer for the Office of Pollution Prevention and Toxics. The exemption notice must be "postmarked" or hand-delivered by the 30th day after manufacture has commenced under the terms of this exemption.

(k) *Exemptions granted under superseded regulations.* Manufacturers holding exemptions granted under the superseded requirements of this section shall either continue to comply with those requirements or submit a new exemption notice pursuant to this section. If an exemption holder continues to follow the superseded regulations, the Notice of Commencement requirements apply and the exempt polymer will continue to be listed on the Inventory with exclusion criteria, exemption category restrictions, and residual monomer and low molecular weight species content limitations.

(l) *Recordkeeping.* (1) A manufacturer of a new polymer under paragraphs (e)(1), (e)(2), or (e)(3) of this section, must retain the records described in this paragraph at the manufacturing site for a period of 5 years from the final date of manufacture.

(2) The records must include the following to demonstrate compliance with the terms of this section:

(i) A copy of the exemption notice.

(ii) Documentation of any other information provided in the limited premanufacture notice, including:

(A) Information to demonstrate that the new polymer is not specifically excluded from the exemption.

(B) Information to demonstrate that the new polymer meets the exemption criteria in paragraphs (e)(1), (e)(2), or (e)(3) of this section including:

(*1*) Detailed batch records including reaction conditions (i.e., temperature, time, etc.) and amount of materials charged to the reactor and appropriate analytical test results for the first batch of the polymer manufactured for distribution in commerce and the initial batch manufactured for distribution in commerce immediately following any change in the polymer manufacturing process that may alter the eligibility of the polymer to meet the criteria at paragraphs (e)(1), (e)(2) or (e)(3) of this section as certified in the exemption notice.

(*2*) An explanation of the submitter's determination that the polymer is exempt under this section. Sufficient written explanation may include conclusions based on: Analytical data, analogies to other similar engineering or chemical processes, or extrapolations from R&D information on the polymer. A new written explanation must be made each time there is a change in manufacturing process that may alter the eligibility of the polymer to meet the criteria at paragraphs (e)(1), (e)(2), or (e)(3) of this section.

(C) If applicable, analytical data to demonstrate that the first batch of new polymer manufactured for commercial purposes under the exemption, and the initial batch manufactured subsequent to a change in manufacturing process that may alter the eligibility of the polymer to meet the criteria at paragraphs (e)(1) or (e)(2) of this section, meets the number-average MW exemption criteria in paragraphs (e)(1) or (e)(2) of this section. The analytical tests may include gel permeation chromatography (GPC), vapor pressure osmometry (VPO), or other such tests

which will demonstrate that the polymer meets the number-average MW criterion.

(D) If applicable, analytical data to demonstrate that the first batch of new polymer manufactured for commercial purposes under the terms of the exemption, and the initial batch manufactured subsequent to a change in manufacturing process that may alter the eligibility of the polymer to meet the criteria in paragraphs (e)(1) or (e)(2) of this section, meets the low MW content criteria in paragraphs (e)(1) or (e)(2) of this section.

(E) If applicable, analytical data required in paragraph (f)(2)(iv)(A) of this section to make an "as incorporated" basis determination for reporting reactants used at greater than 2 weight percent in the manufacture of the polymer.

(iii) Documentation of the nature and method of notification under paragraph (e)(2)(i) of this section including copies of any labels or written notices used.

(iv) If notification is required under paragraph (e)(2)(v) of this section, the names and addresses of any persons other than the manufacturer or importer to whom the substance is distributed and copies of the written notification required under that paragraph.

(v) Records that demonstrate compliance with the requirements of paragraph (e)(2) of this section. Records must demonstrate use of the required respirators under paragraph (e)(2) of this section or information to demonstrate that sufficient workplace controls are in place such that inhalation exposure does not exceed 0.5 mg/m^3 in any 8–hour work shift of a 40–hour work week. Records of any additional results of personal exposure monitoring and any additional information related to worker's occupational exposure which the manufacturer may possess must also be maintained and made available to EPA if requested.

(3) The manufacturer must submit the records listed in paragraph (l)(2) of this section to EPA upon written request by EPA. The manufacturer must provide these records within 15 working days of receipt of this request. In addition, any person who manufactures a new chemical substance under the terms of this section, upon request of EPA, must permit such person at all reasonable times to have access to and to copy these records.

(m) *Submission of information.* Information submitted to EPA under this section must be sent in writing to: Document Control Officer (TS–790), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

(n) *Compliance.* (1) Failure to comply with any provision of this section is a violation of section 15 of the Act (15 U.S.C. 2614).

(2) A person who manufactures or imports a new chemical substance and fails to comply with paragraph (f) of this section is in violation of section 15 of the Act.

(3) Using for commercial purposes a chemical substance or mixture which a person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5 of the Act is a violation of section 15 of the Act (15 U.S.C. 2614).

(4) Failure or refusal to establish and maintain records or to permit access to or copying of records, as required by this section and section 11 of the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(5) Failure or refusal to permit entry or inspection as required by section 11 of the Act is a violation of section 15 of the Act (15 U.S.C. 2614).

(6) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation. Persons who submit materially misleading or false information in connection with the requirements of any provision of this section may be subject to penalties calculated as if they never filed their notices.

(7) EPA may seek to enjoin the manufacture or processing of a chemical substance in violation of this section or act to seize any chemical substance manufactured or processed in violation of this section or take other actions under the authority of section 7 of the Act (15 U.S.C. 2606) or section 17 of the Act (15 U.S.C. 2616).

(o) *Inspections.* EPA will conduct inspections under section 11 of the Act to assure compliance with section 5 and this section, to verify that information submitted to EPA under this section is true and correct, and to audit data submitted to EPA under this section.

(p) *Revocation of exemption.* (1) If at any time after an exemption application has been received under the terms of this section, EPA obtains information (through a TSCA section 8(e) report or through any other source) indicating to EPA that a particular polymer (or category of polymers that includes such polymer) or a reasonably anticipated metabolite or environmental transformation product of the substance may present an unreasonable risk of injury to human health or the environment, EPA shall notify the manufacturer of that polymer, by certified mail, that its exemption under this section will be revoked. The criteria for revocation of the exemption are that the polymer substance or a reasonably anticipated metabolite or environmental transformation product of the substance:

(i) May cause significant chronic effects, including carcinogenic, developmental or reproductive effects, under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the substance.

(ii) May cause significant acute effects (lethal or sublethal) under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new substance.

(iii) May cause significant environmental effects under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the substance.

(2) The manufacturer may continue to manufacture, process, distribute in commerce, and use the substance after receiving the notice under paragraph (p)(1) of this section if the manufacturer was manufacturing, processing, distributing in commerce, or using the substance at the time of the notification and if the manufacturer submits written objections to EPA within 15 days of receipt of the notification. Such written objections must state the reasons why the manufacturer believes that the polymer will not present an unreasonable risk of injury to health or the environment. Manufacturers not manufacturing, processing, distributing in commerce, or using the substance at the time of the notification may not begin manufacture until EPA makes its final determination under paragraph (p)(3) of this section.

(3) EPA will consider any objections submitted under paragraph (p)(2) of this section and will make a final determination on whether to revoke the exemption. EPA will notify the manufacturer of the final determination by certified mail within 15 days of receipt of the objections submitted under paragraph (p)(2) of this section.

(4) Within 24 hours of receipt of a final determination from EPA that an exemption is revoked, the manufacturer of the substance for which the exemption was revoked shall cease all manufacturing, processing, distribution in commerce, and use of that substance. The manufacturer may not resume manufacture, processing, distribution in commerce, or use until it submits a premanufacture notice under section 5(a)(1) of the Act and part 720 of this chapter and the notice review period has ended.

(5) Action under this paragraph does not preclude action under any other applicable sections of the Act.

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